

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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Ex Parte RICHARD C. VOGEL, DAVID M. TUMEY,  
SUSAN P. MORRIS, and L. TAB RANDOLPH

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Appeal No. 2004-\_\_\_\_\_  
Application No. 09/458,280  
Filed: December 10, 1999  
Group Art Unit: 3764  
Examiner: DeMille, Danton D.  
Title: THERAPEUTIC APPARATUS FOR TREATING ULCERS  
Confirmation No.: 8678  
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**APPELLANTS' BRIEF**

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## **I. Real Party in Interest**

KCI Licensing, Inc., is the assignee of the pending application. KCI Licensing, Inc., and the related publicly traded company Kinetic Concepts, Inc., of San Antonio, Texas (ticker: KCI) are the real parties in interest.

## **II. Related Appeals and Interferences**

Appellants, Appellants' legal representative, and KCI Licensing, Inc., are not aware of any other appeals or interferences which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

## **III. Status of Claims**

Claims 1-17 are pending in the application. Claims 1, 10, and 17 are independent. Claims 2-9 and 11-16 depend directly or indirectly from claim 1. Each of claims 1-17 has been rejected. And Applicants appeal the rejections of each of claims 1-17.

## **IV. Status of Amendments**

No amendments to claims 1-17 were filed subsequent to the final rejection dated November 24, 2003.

## **V. Summary of the Invention**

The pending patent application discloses a medical device 200 or 500 comprising a micro-controller unit 203, an air compressor 204, a vacuum pump 212,<sup>1</sup> a porous foam wound dressing 402 for the foot, and a foot compression wrap 301 or 302 for applying compressive force to the foot.<sup>2</sup> In operation, the device 200 or 500 supplies negative (i.e., subatmospheric)

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<sup>1</sup> The air compressor 204 and vacuum pump 212 may be replaced by a single integrated compressor and vacuum pump unit 501 having two separate plenums 502 and 503, one for supplying the wound dressing, and the other for supplying the foot wrap. Page 14, lines 3-11.

<sup>2</sup> Specification, page 8, line 1 – page 9, line 11.

pressure therapy to the wound dressing 402 at the same time as it applies a pneumatic compressive force, in a preferably intermittent fashion, to the foot wrap 301. The micro-controller unit 203, a pressure sensor 227, and a vacuum sensor 228 form feedback control loops to control the operation of the air compressor 204 and vacuum pump 212.<sup>3</sup> Figs. 6A and 6B, reproduced below, illustrate a wound dressing comprising a porous foam dressing 402 that is inserted into the wound site, tubing 403 inserted into the foam dressing 402 for applying subatmospheric pressure, and an adhesive drape 404.

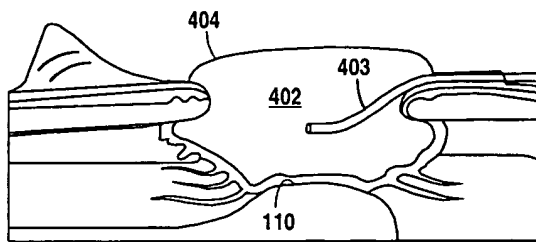


Fig. 6A

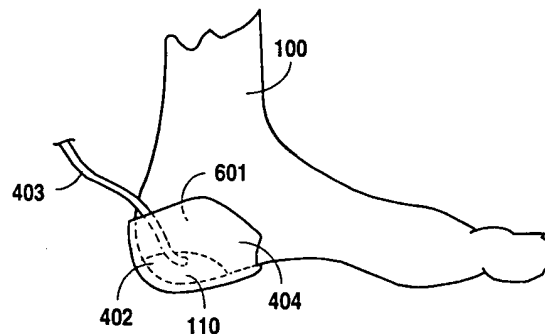


Fig. 6B

The porous foam dressing 402 promotes distribution of subatmospheric pressure throughout the wound site. Fig. 8, also reproduced below, illustrates a combination of the wound dressing (covered by drape 404) and a partially overlapping foot wrap 301.

<sup>3</sup> Specification, page 10, line 11 – page 13, line 23.

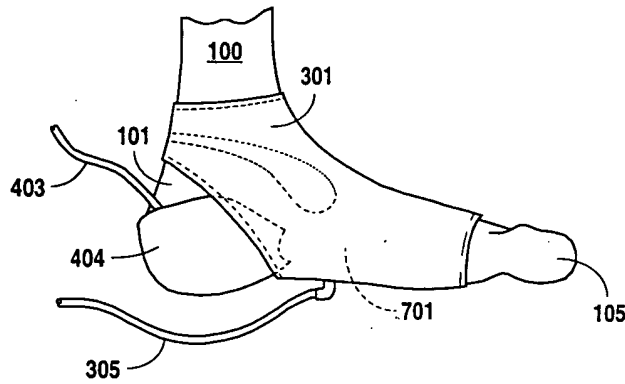


Fig. 8

The purpose of the system 200 or 500 is to promote healing and closure of wounds such as foot ulcers, using subatmospheric pressure to promote vascularization and tissue growth in the wound, while at the same time using positive intermittent compression to prevent venous stasis and promote health blood circulation.<sup>4</sup>

## VI. Issues

A. Are claims 1-5 and 10-17 unpatentable under 35 U.S.C. 103(a) over U.S. Patent No. 5,489,259 to Jacobs et al. in view of U.S. Patent No. 5,645,081 to Argenta et al. and U.S. Patent No. 5,007,411 Dye?

B. Are claims 6, 8, and 9 unpatentable under 35 U.S.C. 103(a) over Jacobs et al. in view of Argenta et al. and Dye and in further view of U.S. Patent No. 5,433,440 ("the '440 patent") to Tumey et al.?

C. Is claim 7 unpatentable under 35 U.S.C. 103(a) over Jacobs et al. in view of Argenta et al., Dye, the '440 patent, and U.S. Patent No. 5,701,917 to Khouri?

D. Are claims 1-6 and 8-17 unpatentable under 35 U.S.C. 103(a) over Jacobs et al. in view of Argenta et al. and U.S. Patent No. 5,840,049 ("the '049 patent") to Tumey et al.?

E. Is claim 7 unpatentable under 35 U.S.C. 103(a) over Jacobs et al. in view of Argenta et al. and the '049 patent and further in view of Khouri?

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<sup>4</sup> Specification, page 2, line 18 – page 4, line 8.

F. Are claims 1-6 and 8-17 unpatentable under the judicially-created doctrine of obviousness-type double patenting over claims 1-8 of the '049 patent in view of Argenta et al. and Jacobs et al.?

G. Is claim 7 unpatentable under the judicially created doctrine of obviousness-type double patenting over claims 1-8 of the '049 patent in view of Argenta et al. and Jacobs et al. and further in view of Khouri?

Jacobs et al., Argenta et al., Dye, the '440 patent, Khouri, and the '049 patent are attached hereto as Exhibits 1, 2, 3, 4, 5, and 6 respectively.

## **VII. Grouping of Claims**

Claims 1-17 do not stand or fall together. Appellants believe that the claims fall into no less than ten separately patentable groups, when compared to the references cited against them:

Group 1: Claim 10.

Group 2: Claim 17.

Group 3: Claims 1-4, 11-13, and 15.

Group 4: Claim 5.

Group 5: Claim 6.

Group 6: Claim 7.

Group 7: Claim 8

Group 8: Claim 9.

Group 9: Claim 14.

Group 10: Claim 16.

## **VIII. Argument**

This appeal comes in response to the fourth office action on the merits rejecting the claims. In each of these office actions, the Examiner rejected all of the pending claims over U.S. Patent No. 5,489,259 to Jacobs et al., entitled "Pressure-Normalizing Single-Chambered Static Pressure Device for Supporting and Protecting a Body Extremity," in combination with other



references. As the prosecution progressed, the Examiner withdrew many of these grounds of rejection in view of various arguments and amendments that were made. But in every case, new grounds of rejection involving other combinations of art replaced the withdrawn grounds of rejection. Jacobs et al. has been the key reference of every ground of rejection.

The Jacobs et al. reference is concerned with preventing heel sores and other sores often experienced by “bedridden patients or those often confined in a supine position.” Col. 1, lines 24-25. The reference explains that “it is common that undue pressure, or simply the weight of the limb itself, is exerted on one area of the limb, particularly the heel and Achilles region, thereby compromising blood circulation to that area and inviting skin and soft tissue breakdown or the formation of pressure sores or other pathologies.” Col. 3, lines 6-10. To prevent such complications, the reference discloses an air pressurizable boot or wrap-like device that is inflated to a “low internal static air pressure of no more than about 0.50 p.s.i., which is sufficient to dissipate and evenly distribute the pressure applied by the device to the limb at the common interface surfaces therebetween.” Col. 2, lines 46-50 (emphasis added). Figure 10 of the reference, reproduced below, best illustrates the device of Jacobs et al.

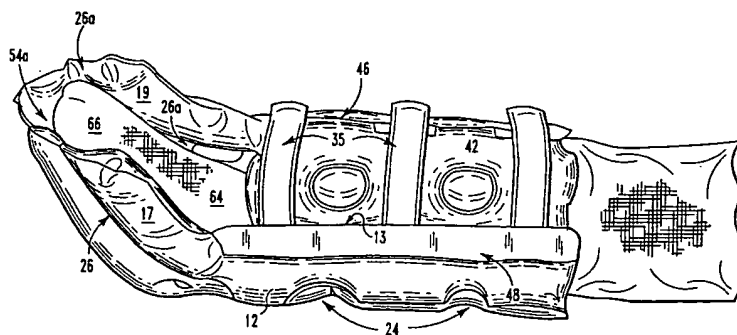


Fig. 10

Fig. 10 of the Jacobs et al. reference

Uniform distribution of low internal static air pressure is the indispensable, *sine qua non* object of the Jacobs et al. reference. See col. 1, lines 10-14, 22-23, 49-51, 56-57. Jacobs et al. criticizes multi-chambered air pressurizable boots “because the separate pressurized chambers prevent the displacement of interior air volume of the device from a region of high pressure to a region of low pressure to thereby normalize and evenly distribute pressure applied by the device to the limb and the effect of gravity acting on the limb.” Col. 1, lines 43-48. By contrast, the “single chamber static air design provided by [the Jacobs et al.] invention allows for a true low-pressure, pressure normalizing system which cannot be as easily achieved with a device having multiple chambers.” Col. 3, lines 12-15. “The single chamber static air design of protective device 10 allows for a true low pressure system that cannot be duplicated by a device having multiple interior inflation chambers. Such multi-chambered devices are unable to achieve the uniformity of overall interface pressure applied by the device to the limb . . . .” Col. 9, lines 23-29. “Thus, the low internal static air pressure of single-chambered device 10 and its method of use provided by this invention dissipates undue pressures and evenly distributes the pressures and forces between device 10 and extremity 60 . . . .” Col. 9, lines 48-52.

**A. Claims 1-5 and 10-17 are patentable over Jacobs et al. in view of Argenta et al. and Dye, because the features of Jacobs et al. are not properly combined with the features of Argenta et al. and Dye and because the references, if combined, do not suggest the claimed subject matter.**

In the final office action November 24, 2003, the Examiner rejected claims 1-5 and 10-17 under 35 U.S.C. § 103(a) over Jacobs et al. in view of U.S. Patent No. 5,645,081 to Argenta et al. and U.S. Patent No. 5,007,411 to Dye. The Examiner cited Jacobs et al. for teaching an inflatable foot wrap for applying compressive force over the lower leg and foot of the patient. The Examiner cited Argenta et al. for teaching a conventional wound dressing that uses a porous foam pad 10 positioned within the ulcer, a drape 12 for covering and sealing the ulcer, and fluid

communication means 11, 15. And the Examiner cited Dye for teaching a conventional pump, reservoir, and valves for supplying pressure to inflation bladders, wherein the valves are closed while compressor 32 charges the accumulator 30 with pressurized gas, and wherein the valve is thereafter opened to permit passage of pressurized fluid from the accumulator 30 into the ankle chamber.

Applicants do not contest these particular statements. But the Examiner advanced no proper justification for combining selected features from these three isolated prior art references to render the claimed invention obvious. And even if the references are combined, taken as a whole, they do not suggest the claimed subject matter. For this rejection to be valid for even the arguably broadest claim (claim 10), the combination of selected features from Jacobs et al., Argenta et al., and Dye would have to yield, among other limitations, an apparatus for treatment of foot ulcers comprising a dressing for applying a subatmospheric pressure to the foot *and* a compressive element for applying superatmospheric compressive force to a compressible region of the foot, *and* a compressor and control circuit to shut off the compressor when a target pressure is reached in the compressive element. This ground of rejection is improper and cannot stand.

**1. Jacobs et al. is not properly combined with Argenta et al.**

Jacobs et al.'s teachings do not withstand, much less suggest, combination with Argenta et al. As noted above, Jacobs et al. is obsessively concerned with providing an *even, uniform distribution* of low internal static *air pressure* to a single-chambered air pressurizable boot or wrap-like device. To combine it with Argenta et al., which teaches application of subatmospheric pressure to a wound site (see abstract), would defeat Jacobs et al.'s goal of achieving even, uniform distribution of air. Jacobs et al.'s teachings and its unrelenting criticism of differentially pressured multi-chambered devices are contrary and opposite to the claimed

invention's differential application of subatmospheric and superatmospheric pressures to different or overlapping regions of the foot.

The ever-so-brief mention of the two words "medical dressings" in the following passage in Jacobs et al. does not sustain the Examiner's proposed combination of Jacobs et al. positive pressure device with Argenta et. al.'s subatmospheric pressure wound dressing apparatus:

The VELCRO® closure means provided by this invention also serves as a pressure relief safety system in that in the event of acute lower limb swelling, the fasteners will pull or come apart thereby preventing the possibility of the device having a tourniquet effect on the swelling limb. Such a phenomenon can occur in the event of a blood clot forming in the limb or from congestive heart failure. The releasable securing means thus allows for easy "put on" and "take off" of the device 10 and facilitates the changing process of any medical dressings applied to the lower limb, allows for minor adjustments in the degree to which the device is secured about the lower limb (i.e., tighter or looser) without the care giver having to add or subtract air from within the inflatable member 12, and allows for quick one-handed peel-away release in emergency situations. (Col. 5, line 65 – col. 6, line 12).

It cannot reasonably be asserted that to a person of ordinary skill in the art, Jacobs et al.'s generic reference to "medical dressings" constitutes a specific teaching or suggestion to use a subatmospheric pressure wound dressing.

Subatmospheric pressure wound dressings are a relatively new and highly specialized kind of medical dressing. See Argenta, L.C., Morykwas, M.J. *Vacuum assisted closure: A new method for wound control and treatment: Clinical experience*, ANNALS OF PLASTIC SURGERY, 1997; 38(6): 563-77 (Exhibit 7). It cannot be said that at the time the claimed invention was filed (which claims priority to July 28, 1997 and July 30, 1997), or even today, medical dressings "conventionally" then took or today take the form of subatmospheric pressure wound dressings. The inventors of the Jacobs et al. reference almost certainly did not have Argenta et al.'s breakthrough invention in mind when they filed their application (Oct. 27, 1993). If they did

contemplate its use with their invention, the ever-so-brief mention of “medical dressings” in their patent provides no hint of it.

In *Graham v. John Deere Co.*, the Supreme Court cautioned officials “to resist the temptation to read into the prior art the teachings of the invention at issue.”<sup>5</sup> But the Examiner succumbed to that temptation by reading the concept of “negative pressure wound dressings” into Jacobs et al.’s mention of “medical dressings.”

To determine what a person of ordinary skill in the art would comprehend by Jacobs et al.’s “medical dressings” reference, it is useful to consult dictionaries. The Fourth Edition (1994) of Mosby’s Medical, Nursing & Allied Health Dictionary defines “dressing” as “a clean or sterile covering applied directly to wounded or diseased tissue for absorption of secretions, for protection from trauma, for administration of medications, to keep the wound clean, or to stop bleeding.” (Exhibit 8). It states that “[k]inds of dressings include absorbent dressing, antiseptic dressing, occlusive dressing, pressure dressing, and wet dressing,” each of which are further defined as follows:

Medical Term	Definition
Absorbent dressing	“a dressing of any material applied to a wound or incision to absorb secretions”
Antiseptic dressing	“a dressing treated with an antiseptic, germicide, or bacteriostat, applied to a wound or an incision to prevent or treat infection.”
Occlusive dressing	“a dressing that prevents air from reaching a wound or lesion and that retains moisture, heat, body fluids, and medication. It may consist of a sheet of thin plastic affixed with transparent tape.”
Pressure dressing	“a dressing firmly applied to exert pressure, usually on a wound for hemostatis.”
Wet dressing	“a moist dressing used to relieve symptoms of some skin diseases. As the moisture

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<sup>5</sup> *Graham v. John Deere Co.*, 383 U.S. 1, 36 (1966).

	evaporates, it cools and dries the skin, softens dried blood and sera, and stimulates drainage. Medication may be added if necessary.”
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Although this reference describes a variety of types of medical dressings, it does not acknowledge or categorize dressings to which subatmospheric pressure or suction is applied.

General-use dictionaries also fail to acknowledge or categorize dressings designed for the application of subatmospheric pressure or suction. The Tenth edition of Merriam-Webster’s Collegiate Dictionary broadly defines a “dressing” as a “material (as ointment or gauze) applied to cover a lesion.” (Exhibit 9). The 2001 edition of Microsoft’s Encarta College Dictionary defines a “dressing” as “a bandage or other sterile covering that is put on a wound to protect it from infection or further damage.” (Exhibit 10). Webster’s Third New International Dictionary of the English Language (Unabridged) defines a dressing as “something used as a cleaning or conditioning agent, as material (as ointment, gauze) applied to cover a sore, wound, or other lesion.” (Exhibit 11). It also defines a “pressure dressing” as “a thick pad of gauze or other material placed over a wound and affixed firmly so that it will exert pressure – called also a compression dressing.” (Exhibit 11). None of these definitions teach or suggest the particular use of subatmospheric pressure wound dressings, as claimed.

Contemporaneous patent references also describe conventional “medical dressings” in generic terms that do not teach or suggest the particular use of subatmospheric pressure wound dressings, as claimed. U.S. Patent No. 4,829,995 describes “a bandage or gauze pad” as an example of a “conventional medical dressing.” Col. 1, lines 45-49 (Exhibit 12). U.S. Patent No. 5,003,971 states that “[c]onventional medical dressings often have a gauze layer which attempts to fulfill a dual function of permitting air to flow to and from the heal area and to absorb liquid type materials from the wound.” Col. 1, lines 50-53 (Exhibit 13). Notably, U.S. Patent No.

5,792,088 describes several different kinds of “medical dressings” without ever mentioning the existence of negative or subatmospheric pressure wound dressings:

Surgical dressings, compression dressings, and support garments are commonly used in all types of medical procedures for the multiple purposes of protecting a wound or incision, applying pressure to the treated area, and absorbing bodily fluids. For purposes of this specification the term “medical dressing” is intended to cover all types of dressings, including surgical dressings, compression dressings, absorbent dressings, support garments, etc. Medical dressings, in general, are individually packaged in sterile packages for easy availability and application. Use of the existing medical dressings normally requires opening of the sterile package, and application of the dressing to the subject area after the medical procedure is completed. Col. 1, lines 9-21 (Exhibit 14).

Because medical dressings were and are “conventionally” used without the application of subatmospheric pressure at the time of the invention, Jacobs et al.’s mention of its compatibility with the use of “medical dressings” does not suggest, teach or motivate combination with Argenta et al. Rather, Jacobs et al.’s insistence on an even, uniform distribution of air pressure teaches away from such a combination.<sup>6</sup>

**2. Jacobs et al. is not properly combined with Dye.**

Jacobs et al.’s teachings also cannot withstand a combination with Dye. Jacobs et al. is interested in maintaining a static air pressure, and it teaches the use of a recessed one-way air valve to maintain that air pressure, to which air may be added or released to achieve a customized degree of inflation. Col. 4, lines 24-27, col. 6, lines 36-39. Jacobs et al. does not teach or suggest that a person of ordinary skill in the art regulate the pressure in Jacobs et al.’s foot wrap or boot-like device using an “automatic positive pressure source.” Such a suggestion would obviate the apparent need and benefit of using a “one way valve.” But even assuming this teaching was ignored, a person of ordinary skill in the art would not likely conclude that Dye’s

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<sup>6</sup> See *In re Kotzab*, 217 F.3d 1365, 1371 (Fed. Cir. 2000) (holding that individual statements in a reference cannot be taken out of context but instead “must be considered in the context of the teaching of the entire reference”).

pump and control system was a suitable automatic positive pressure source for Jacobs et al.'s "pressure-normalizing single-chambered static pressure device."

Dye teaches a multi-chambered sequential compression sleeve for a leg that utilizes a compressor 32 inside an accumulator 30 to carry out intermittent sequential compression cycles. See Abstract; col. 3, lines 54-57; Figs. 1, 2, 4. Dye does not supply Jacobs et al. with means of achieving its goal of even, uniform distribution of air. Rather, the combination of Jacobs et al. with Dye would convert Jacobs et al.'s "static pressure" device into an intermittent compression device, contrary to Jacobs et al.'s teachings.

The Federal Circuit unequivocally "forbids the use of hindsight in the selection of references that comprise the case of obviousness."<sup>7</sup> And "[i]t is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art."<sup>8</sup> Hindsight alone inspired the Examiner's remark that "[i]t would have been obvious to one of ordinary skill in the art to modify Jacobs to use a conventional wound dressing such as taught by Argenta in combination with the foot wrap as suggested by Jacobs and to use automatic positive automatic pressure source as taught by Dye to automatically regulate the pressure within the inflatable foot wrap."<sup>9</sup> Clearly, when one takes the teachings of Jacobs et al., Argenta et al., and Dye "as a whole," without the benefit of hindsight, no motivation, teaching, or suggestion can be found for such a

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<sup>7</sup> *In re Rouffet*, 149 F.3d at 1358.

<sup>8</sup> *In re Hedges*, 783 F.2d 1038, 1041 (Fed. Cir. 1986).

<sup>9</sup> Final Office Action, at 2-3. See *In re Rouffet*, 149 F.3d 1350, 1358 (Fed. Cir. 1998) (holding that "this court infers that the examiner selected these references with the assistance of hindsight" where no explanation was provided of "the specific understanding or principle within the knowledge of a skilled artisan that would motivate one with no knowledge of [the claimed] invention to make the combination" as claimed).



dramatic modification of Jacobs et al. to cover the claimed invention. Furthermore, and as mentioned previously, Argenta et al. does not describe a *conventional* dressing.

**3. “Mere” (yet novel) combinations of old elements can be patented.**

The real force behind the Examiner’s rejection is the conviction that mere combinations of old elements are not worthy to be patented.<sup>10</sup> On page 3 of the office action, the Examiner argues that “[i]t appears that applicant has merely taken individual conventional elements and stuck them together.” On page 5, the Examiner repeats this objection:

It is felt that the claims merely recite a combination of conventional elements. The inflatable foot wrap is not new. The vacuum wound dressing is not new. Even the newly claimed compressor and reservoir is not new. Applicant appears to be combining old elements together for a specific intended use. There is no unobviousness to combine these elements together since the prior art even suggests it.

Applicants agree that many of the elements of the claims are individually represented in isolated, unrelated prior art references. But that does not render the claimed invention obvious.

“Most if not all inventions arise from a combination of old elements.”<sup>11</sup> “If identification of each claimed element in the prior art were sufficient to negate patentability, very few patents would ever issue.”<sup>12</sup> The Federal Circuit has time and again categorically rejected the mere-combinations-cannot-be-patented concept underlying the Examiner’s rejection of the instant application’s claims.<sup>13</sup>

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<sup>10</sup> Applicants do not concede that the claimed invention constitutes a “mere” – as in “trivial” – combination. It is a medically useful combination providing nontrivial benefits to patients suffering from severe venous deficiency disorders – including patients for whom traditional compression therapy would be contraindicated.

<sup>11</sup> *In re Kotzab*, 217 F.3d 1365, 1369 (Fed. Cir. 2000).

<sup>12</sup> *In re Rouffet*, 149 F.3d 1350, 1357 (Fed. Cir. 1998).

<sup>13</sup> See, e.g., *Fromson v. Advance Offset Plate*, 755 F.2d 1549, 1556 (Fed. Cir. 1985) (holding that “[t]here is no basis in the law . . . for treating combinations of old elements differently in determining patentability” than any other claim).

Interestingly, the Examiner's no-patents-for-mere-combinations position heralds back to a bygone era famous for its inhospitality to patents. In 1950, the Supreme Court held that claims involving combinations of known elements could not be patented unless "the whole in some way exceeds the sum of its parts" and the combination yields some "unusual or surprising result."<sup>14</sup> Fortunately, this rule was overturned with the passage of the 1952 Patent Act and the Supreme Court's 1964 *Graham* decision. Since then, the Federal Circuit and its predecessor courts "have considered and rejected the notion that a new result or function or synergism is a requirement of patentability."<sup>15</sup> As the Federal Circuit explained in *Chore-Time Equip., Inc. v. Cumberland*, such a requirement has no basis in the text of the Patent Act:

A requirement that an invention reflect 'synergism' or achieve a 'synergistic result,' before it may be held patentable appears nowhere in the statute, 35 U.S.C. The test of obviousness under 35 U.S.C. § 103, as the statute makes plain, is whether the invention as a whole would have been obvious at the time it was made to one of ordinary skill in the art.<sup>16</sup>

It is valuable to revisit the rationale for making patent protection *readily* available to innovators for their advancements and improvements on the prior art. Readily available protection spurs investment in innovation. Making patent protection exceptionally difficult to obtain and enforce will discourage such investments.<sup>17</sup>

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<sup>14</sup> *Great Atlantic and Pacific Tea Co. v. Supermarket Eq. Corp.*, 340 U.S. 147, 152 (1950).

<sup>15</sup> *American Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1360 (Fed. Cir. 1984).

<sup>16</sup> *Chore-Time Equip., Inc. v. Cumberland*, 713 F.3d 774, 781 (Fed. Cir. 1983).

<sup>17</sup> Conversely, it is true that monopolies discourage competition. But the Patent Act, as required by the Constitution, strikes the balance between encouraging innovation and promoting competition by preserving the exclusive right for only a "limited time."

It is notable to consider what life was like before the development of robust patent protection systems. In his best-selling book *The Birth of Plenty: How the Prosperity of the Modern World Was Created*, author William J. Bernstein remarked that "[t]he list of significant mechanical inventions prior to 1700 is a short one: The windmill, the waterwheel, and the printing press pretty well exhaust the roll call." WILLIAM J. BERNSTEIN, *THE BIRTH OF PLENTY: HOW THE PROSPERITY OF THE MODERN WORLD WAS CREATED* 93 (2004). But the past three centuries' recognition of patent rights have unleashed humankind's innovative potential and resulted in extraordinary and unprecedented progress in humankind's material well-being:

Novel combinations of old elements cannot be rejected as obvious merely because they are combinations of old elements. “[I]nvention itself is the process of combining prior art in a nonobvious manner.”<sup>18</sup> The mere fact that the prior art *can* be combined or modified does not render the resultant combination or modification obvious.<sup>19</sup> “The critical inquiry is whether ‘there is something in the prior art as a whole to suggest the desirability, and thus the obviousness, of making the combination.’”<sup>20</sup> Although a prior art reference “may be capable of being modified to run the way [an] apparatus is claimed, there must be a suggestion or motivation in the reference to do so.”<sup>21</sup>

To sustain an obviousness rejection, an examiner “must show reasons that the skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed.”<sup>22</sup> More particularly, the examiner “must identify specifically the principle, known to one of ordinary skill, that suggests the claimed combination.”<sup>23</sup> The Federal Circuit requires “rigorous application of the requirement for a showing of the teaching or motivation to

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Beginning about 1730, the world saw an unprecedented burst of technological innovation. It has continued to the present day and owes itself in no small measure to the birth of patent law. Economist Douglass North points out that inventions produce both private and social benefit – they profit society as well as the inventor. If the law does not reserve a high enough share of that bounty for the inventor, he will not invent. By generously rewarding the inventor, society rewards itself. No sane person expends the enormous amount of capital, time, and effort involved in the creation and mass production of an invention if others can knock it off without penalty. *Id.* at 82.

<sup>18</sup> *In re Rouffet*, 149 F.3d 1350, 1359 (Fed. Cir. 1998).

<sup>19</sup> *In re Mills*, 916 F.2d 680, 682 (Fed. Cir. 1990); *In re Gordon*, 733 F.2d 900, 902 (Fed. Cir. 1984).

<sup>20</sup> *Fromson v. Advance Offset Plate*, 755 F.2d 1549, 1556 (Fed. Cir. 1985) (quoting *Lindeman Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1462 (Fed. Cir. 1984)).

<sup>21</sup> *In re Mills*, 916 F.2d 680, 682 (Fed. Cir. 1990) (emphasis added).

<sup>22</sup> *In re Rouffet*, 149 F.3d 1350, 1357 (Fed. Cir. 1998) (emphasis added).

<sup>23</sup> *Id.* at 1359.

combine prior art references” as an antidote to “the subtle but powerful attraction of a hindsight-based obviousness analysis.”<sup>24</sup>

Because none of the cited references supply any motivation, teaching, or suggestion for combining Jacobs et al. with Argenta et al.’s unconventional and new subatmospheric pressure device and with Dye’s multi-chambered intermittent sequential pressure device in the manners claimed, the rejections based on this combination of references cannot be sustained.

**4. The combination of the references as a whole does not suggest the subject matter of any of the claims.**

Even if the references taken as a whole *were* combined, they would not suggest the claimed subject matter. Independent claims 1, 10, and 17 all recite “a control circuit for shutting off said compressor when said target pressure is reached.” None of the cited references, including Dye, suggest the same.

During the first ten seconds of a cycle, Dye’s four valves 34a, 34b, 34c and 34d are closed to allow the compressor 32 to build up pressure in the accumulator 30 over time. Col. 3, lines 1-7. Then, the ankle chamber valve 34a, calf chamber valve 34c, thigh chamber valve 34d, and foot and knee chamber valve 34b are sequentially opened for “spaced intervals of time” that are “specified” or predetermined in advance. Col. 3, lines 54-67. Then the valves are closed and the cycle repeats itself. The pressure in each of the chambers continually changes, as illustrated by the pressure curves or profiles 50, 54, 57, and 94 of each of the chambers.

Meanwhile, Dye’s compressor “continues to remain in operation” throughout the entire cycle. Col. 4, lines 14-16. The pressure curve or profile 52 of the accumulator 30 in Fig. 6 illustrates the non-stop operation of the compressor. The pressure curve or profile 52 initially

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<sup>24</sup> *In re Dembiczak*, 175 F.3d at 999 (emphasis added).

drops when one of the valves 34a, 34c, or 34d is opened, but begins to rise again after the pressure in the accumulator 30 and the then-connected chambers reach equilibrium. The pressure would not rise in the chamber unless the compressor stayed in operation. Thus, Dye does not disclose or teach a control circuit to shut off the compressor 32 after the accumulator 30 reaches a target pressure, as claimed in each of the rejected claims.

**5. Claims 1-5 and 11-17 are separately patentable from claim 10.**

Claims 1-5 and 11-17 are separately patentable from claim 10 because they recite that the wound dressing is comprised of porous foam positioned within the foot ulcer, a drape for covering and sealing the foam within said foot ulcer, and a fluid communications means in fluid communication with said foam. The purpose of the porous foam limitation is to evenly distribute the subatmospheric pressure within the wound. Because “conventional” medical dressings utilize gauze or an overlying bandage,<sup>25</sup> the “porous foam” and “drape” limitations further differentiate claims 1-5 and 11-17 from Jacobs et al, the principal reference used in the Examiner’s rejection.

Furthermore, claims 1-5 and 11-17 expressly require that the apparatus includes a *foot wrap* having an inflatable bladder. Prior art foot compression art teaches away from applying a foot wrap to an open wound or ulcer on the foot. In their article “The Effect of a Mechanical Venous Pump on the Circulation of the Feet in the Presence of Arterial Obstruction,” in the April 1978 issue of the Journal of Surgery, Gynecology & Obstetrics (Exhibit 15, which was submitted in an IDS in the parent application), authors Dr. Gaskell and Dr. Parrott describe an inflatable *single-walled* boot for treating lesions and rest pain in the feet. Toward the end of their article

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<sup>25</sup> See *supra* pages 9-11.

they expressly taught away from applying a double-walled inflation device (such as a foot wrap) to a wound because of the resulting trauma:

The form of the boot used to provide the pumping deserves comment. We consider that a double walled boot, inflated so that the inner wall is pressed to the skin, may distort and traumatize tissue which already has poor nutrition and healing properties. Pressure of air directly on the foot should be less disturbing.<sup>26</sup>

Indeed, this teaching would not motivate persons of ordinary skill in the art at the time the invention was made to combine a foot wrap that presses against the skin with a positive compressive force on a foot with a wound dressing for applying negative or subatmospheric pressure to an open wound on that foot.

**6. Claims 1-5 and 11-16 are separately patentable from claims 10 and 17.**

Claims 1-5 and 11-16 are separately patentable from claims 10 and 17 because they recite “concurrent” introduction of subatmospheric and superatmospheric pressure. The “concurrent” introduction of subatmospheric and superatmospheric pressure is not taught or suggested by any of the cited references, individually or in combination.

**7. Claims 14 and 16 are separately patentable.**

Claim 14 is separately patentable because it recites intermittent positive pressure application by the foot wrap concurrent with that subatmospheric pressure application to the wound dressing. Claim 16 is separately patentable because it recites the intermittent application of subatmospheric pressure to the wound dressing concurrent with the application of positive pressure to the foot wrap. Jacobs et al., the Examiner’s primary reference, insists on static pressure application, thus teaching away from intermittent positive or negative pressure applications. The “concurrent” introduction of subatmospheric with intermittent

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<sup>26</sup> See P. Gaskell, M.D., and J.C.W. Parrott, M.D., *The Effect of a Mechanical Venous Pump on the Circulation of the Feet in the Presence of Arterial Obstruction*, 146 SURGERY, GYNECOLOGY & OBSTETRICS 583, 592 (1978).

superatmospheric pressure, or of intermittent subatmospheric with superatmospheric pressure, is not taught or suggested by any of the cited references, individually or in combination.

**B. Claims 6, 8, and 9 are patentable over Jacobs et al. in view of Argenta et al. and Dye and in further view of the '440 patent.**

The Examiner rejected claims 6, 8 and 9 under 35 U.S.C. § 103(a) as being unpatentable over Jacobs et al. in view of Argenta et al. and Dye and in further view of the '440 patent. The Examiner reasoned that "Tumey teaches a controller 44 and processor 70 for controlling the operation of inflation." The Examiner further reasoned that "[i]t would have been obvious to one of ordinary skill in the art to further modify Jacobs to provide a controller and processor as taught by Tumey to better control the operation of the device." For at least the reasons set forth below, this ground of rejection cannot stand.

**1. Dependent claims 6, 8 and 9 are patentable for the same reasons that parent claims 1 and 5 are patentable.**

It is well established that if a base claim is patentable over the prior art, then its dependent claims are also patentable over the prior art.<sup>27</sup> Claim 6 depends from claim 5, which depends from claim 1. Claims 8 and 9 depend from claim 6. Therefore, claims 6, 8 and 9 are patentable over Jacobs et al. in view of Argenta et al. and Dye and in further view of the '440 patent for all of the previously-expressed reasons that claims 1 and 5 are patentable over Jacobs et al. in view of Argenta et al. and Dye.

**2. Jacobs et al. is not properly combined with the '440 patent.**

Jacobs et al.'s teachings also do not suggest and cannot withstand a combination with the '440 patent. The '440 patent provides "an inflatable bag having first and second bladders for

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<sup>27</sup> *In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992).

applying distinct compressive pressures to separate portions of a foot.”<sup>28</sup> “Further provided is a fluid generator for cyclically inflating and deflating the bag.”<sup>29</sup> Thus, the combination of Jacobs et al. with the intermittent compression controller 44 and processor 70 of the ‘440 patent would defeat Jacobs et al.’s goal of achieving even, uniform distribution of air, and would convert Jacobs et al.’s “static pressure” device into an intermittent compression device, in direct contradiction of Jacobs et al.’s teachings.

Applicants dispute the Examiner’s remark that “[i]t would have been obvious to one of ordinary skill in the art to further modify Jacobs to provide a controller and processor as taught by Tumey to better control the operation of the device.”<sup>30</sup> But when one takes the teachings of Jacobs et al., Argenta et al., Dye, and the ‘440 patent “as a whole,” without the benefit of hindsight, no motivation, teaching, or suggestion can be found for modifying Jacobs et al. *and* the ‘440 patent to make a combination of a foot wrap, a wound dressing, and a control system for applying positive force to the foot wrap *and* negative pressure to the wound dressing. The Examiner’s remark was based on forbidden hindsight.

**3. The combination of references as a whole does not suggest the subject matter of claim 6 or its dependent claims.**

The Examiner’s combination of Jacobs et al., Argenta et al., Dye, and the ‘440 patent does not suggest the subject matter of claim 6 or its dependent claims. Claim 6 recites the additional element of a “control system for defining the negative application of pressure to said wound dressing and the positive application of force to said foot wrap.” The ‘440 patent teaches a control system for intermittent superatmospheric compression of a foot bladder. Neither the

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<sup>28</sup> Col. 1, line 67 – col. 2, line 2.

<sup>29</sup> Col. 2, lines 7-8 (emphasis added).

<sup>30</sup> Final Office Action, at 3.



'440 patent nor any of the other cited references teach or suggest a common control system to control the application of *both* a compressive force to a foot wrap and a suction force to a wound dressing.

**4. The combination of references as a whole does not suggest the subject matter of claim 9.**

Claim 9 recites the additional limitations of "said suction pump and said ventable source of pressurized gas comprise a single integrated processor and vacuum pump unit" and "said control system controls said integrated compressor and vacuum pump unit responsive to both negative pressure supplied to said wound and positive force supplied to said foot wrap." Argenta et al. teaches the use of a suction pump. The '440 patent teaches the use of a pressure-feedback-controlled compressor for inflating a footwrap. But none of the references teach or suggest "a single integrated processor and vacuum pump unit" that is "responsive to both negative pressure supplied to said wound and positive force supplied to said foot wrap."

**C. Claim 7 is patentable over Jacobs et al. in view of Argenta et al., Dye, the '440 patent, and Khouri.**

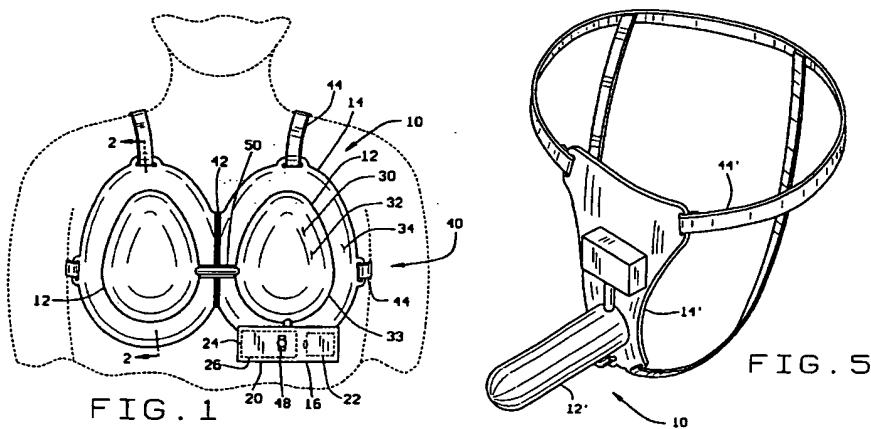
The Examiner rejected claim 7 under 35 U.S.C. § 103(a) as being unpatentable over Jacobs et al. in view of Argenta et al., Dye, the '440 patent, and Khouri. The Examiner reasoned that Khouri teaches "a pressure sensor 24 in the vacuum environment and wound dressing figure 6." The Examiner further reasoned that "[i]t would have been obvious to one of ordinary skill in the art to further modify Jacobs to include a pressure sensor as taught by Khouri to maintain proper pressure within the application site."

1. **Dependent claim 7 is patentable for the same reasons that parent claims 1, 5, and 6 are patentable.**

It is well established that if a base claim is patentable over the prior art, then its dependent claims are also patentable over the prior art.<sup>31</sup> Claim 7 depends from claim 6, which depends from claim 5, which depends from claim 1. Therefore, claim 7 is patentable over Jacobs et al. in view of Argenta et al., Dye, and the '440 patent, and in further view of Khouri for all of the previously-expressed reasons that claims 1 and 5 are patentable over Jacobs et al. in view of Argenta et al. and Dye and for all of the previously expressed reasons that claim 6 is patentable over Jacobs et al. in view of Argenta et al. and Dye, and in further view of the '440 patent.

2. **Khouri is not properly combined with the other four cited references.**

Khouri teaches a medical device to apply vacuum pressure to part of the body, most especially for breast and penis augmentation, but also for an open wound. Khouri's preferred embodiments are illustrated by figures 1 and 5, reproduced below.

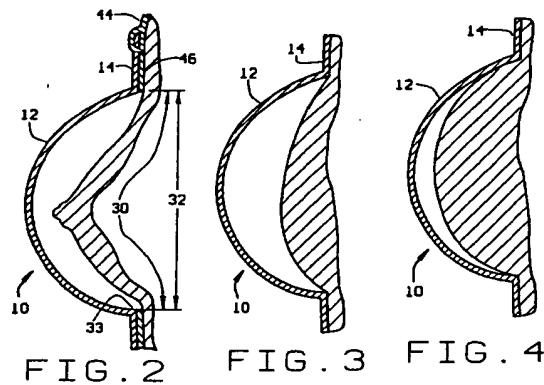


Khouri's medical device comprises a "rigid fluid-impervious dome" (col. 3, line 38) and a vacuum pump assembly 16. A pressure sensor 54 helps maintain negative long-term pressures of no more than 25-35 mm Hg below atmospheric pressure, although to "promote more rapid

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<sup>31</sup> *In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992).

tissue enlargement,” “a ‘cycling’ regimen may be provided” where “the vacuum pump [is] controlled to develop a [negative] pressure as high as 100 mm Hg for several minutes and then return to a much lower level.” Col. 4, lines 20-46; col. 6, lines 8-14. As the apparatus applies negative pressure to the person’s organ, it enlarges to fill the dome, as illustrated by Figs. 2-4 below:



Khoury devotes only two sentences of its detailed description to the less interesting application of his device to an open wound: “As shown in FIG. 6, a dome 52 may be conveniently located over an open wound 54. A pump 56 (including an appropriate control) draws a vacuum through a connecting tube 58 in substantially the same manner as has been explained above.” Col. 5, lines 50-54.

Khoury makes no suggestion that porous foam, which would impede enlargement of the tissue, be placed in the open wound when used with his device. In the background section, Khoury criticizes the use of an “occlusive, or airtight, dressing covering of the wound coupled with suctioning of fluid from the wound” because, among other things, it “is not focused on soft tissue enlargement.” Col. 3, lines 16-30. These teachings are inconsistent with parent claim 1’s recitation of a “wound dressing ... comprised of a porous foam positioned with said foot ulcer” and “a drape for covering and sealing said foam within said foot ulcer.”

It is notable that the Examiner relied on a combination of no fewer than five isolated references to reject claim 7. These references do not serve similar functions. The combination starts with Jacobs et al., which is directed to a “pressure-normalizing single-chambered static pressure device for supporting and protecting a body extremity,” most especially the foot or lower leg. The combination includes Dye, which is directed to a sequential intermittent compression device for the lower leg. Then, as if this mix was not already intriguing enough, the combination incorporates Khouri’s organ tissue enlargement device.

The Examiner’s rejections “presuppos[e] that the person of ordinary skill would necessarily pick and choose among the multitude of disclosures to combine them exactly as did the inventor[s].”<sup>32</sup> But the Federal Circuit has repeatedly held that “[o]ne cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention.”<sup>33</sup> “It is [also] impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art.”<sup>34</sup> The Examiner’s rejection of claim 7 based in part on the Khouri reference should be reversed.

**D. Claims 1-6 and 8-17 are patentable over Jacobs et al. in view of Argenta et al. and the ‘049 patent, because the features of Jacobs et al. are not properly combined with the features of Argenta et al. and the ‘049 patent.**

The Examiner rejected claims 1-6 and 8-17 under 35 U.S.C. 103(a) as being unpatentable over Jacobs et al. in view of Argenta et al. and the ‘049 patent. This rejection fails for the same

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<sup>32</sup> *Henkel Corp. v. Coral Inc.*, 754 F.Supp. 1280, 1316 (N.D. Ill. 1990).

<sup>33</sup> *In re Fine*, 837 F.2d 1071, 1075 (Fed. Cir. 1988); *accord*, *In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992); *see also Polaroid Corp. v. Eastman Kodak Co.*, 789 F.2d 1556, 1571 (Fed. Cir. 1986) (refusing invitation to “pick and choose individual elements from three prior art patents and thereby re-create the invention”).

<sup>34</sup> *In re Hedges*, 783 F.2d 1038, 1041 (Fed. Cir. 1986).

reasons expressed above.<sup>35</sup> First, Jacobs et al. is not properly combined with Argenta et al. for all of the previously noted reasons. Second, Jacobs et al. is not properly combined with the '049 patent for the same reasons that it cannot properly be combined with Dye.

As noted earlier, Jacobs et al. teaches maintenance of a static air pressure and the use of a recessed one-way air valve to maintain that air pressure. Air may be added or released to achieve a customized degree of inflation.<sup>36</sup> Jacobs et al. does not suggest that a person of ordinary skill in the art regulate the pressure in Jacobs et al.'s foot wrap or boot-like device using an "automatic positive pressure source," inasmuch as this would obviate the apparent need and benefit of using a "one way valve."

But even assuming this teaching was ignored, a person of ordinary skill in the art would not reasonably conclude that the '049 patent's pump and control system was a suitable automatic positive pressure source for Jacobs et al.'s "pressure-normalizing single-chambered static pressure device." The '049 patent teaches a two-chambered boot 20 that utilizes a fluid generator 40 to cyclically generate fluid pulses during periodic inflation cycles.<sup>37</sup> Thus, the combination of Jacobs et al. with the '049 patent would convert Jacobs et al.'s "static pressure" device into an intermittent compression device, contrary to Jacobs et al.'s teachings.

Because neither the combination of Jacobs et al. with Argenta et al., nor the combination of Jacobs et al. with the '049 patent is sustainable, and because there is no other motivation, teaching or suggestion in the art expressed for combining selected features of these isolated references together, this ground of rejection cannot stand.

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<sup>35</sup> For purposes of claim grouping, the arguments set forth in argument section A, parts 5-7, are incorporated herein by reference.

<sup>36</sup> Col. 4, lines 24-27, col. 6, lines 36-39.

<sup>37</sup> Col. 4, lines 24-37; Fig. 4.

**E. Claim 7 is patentable over Jacobs et al. in view of Argenta et al. and the '049 patent, and in further view of Khouri, because the selected features of these isolated references not properly combined together.**

The Examiner rejected claim 7 under 35 U.S.C. 103(a) as being unpatentable over Jacobs et al. in view of Argenta et al. and the '049 patent, and in further view of Khouri. This rejection fails for the same reasons expressed in sections A, C, and D above.

**F. Claims 1-6 and 8-17 are patentable over claims 1-8 of the '049 patent in view of Argenta et al. and Jacobs et al.**

The Examiner rejected claims 1-6 and 8-17 as invalid for obviousness-type double patenting over the '049 patent in view of Argenta et al. and Jacobs et al. The Examiner reasoned that "Turney teaches an inflatable foot wrap with a compressor and reservoir as claimed and adding a wound dressing as taught by Argenta would have been an obvious provision if the injury to the leg requires a wound dressing."<sup>38</sup> On the basis of Jacobs et al., the Examiner urged that "the combination of inflatable foot wrap and wound dressing is old."

But the Examiner's double-patenting rejection cannot be sustained on the merits.<sup>39</sup> Jacobs et al. does not teach the claimed combination of a foot wrap with a *subatmospheric* pressure wound dressing. There is no motivation, teaching, or suggestion in the prior art (Argenta et al. and Jacobs et al.) to vary the invention defined by the '049 patent's claims to read on the claimed subject matter of the instant application.

The Federal Circuit recently noted three differences between an obviousness-type double-patenting analysis and the traditional 103(a) obviousness analysis:

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<sup>38</sup> Final Office Action, at 4.

<sup>39</sup> If the double-patenting rejection is sustained but the claims are otherwise allowable, Applicants wish to reserve the right to tender a terminal disclaimer to overcome the rejection.

1. The objects of comparison are very different: Obviousness compares claimed subject matter to the prior art; nonstatutory double patenting compares claims in an earlier patent to claims in a later patent or application;

2. Obviousness requires inquiry into a motivation to modify the prior art; nonstatutory double patenting does not;

3. Obviousness requires inquiry into objective criteria suggesting non-obviousness; nonstatutory double patenting does not.<sup>40</sup>

It is plain that inquiry into motivation is not required by statute, because 35 U.S.C. § 103(a) does not apply.<sup>41</sup> But the Federal Circuit did not clearly articulate an alternative test for obviousness that does not depend on demonstrating some motivation or suggestion to modify the previously claimed subject matter to cover the newly claimed subject matter. The Federal Circuit did, however, stress that the doctrine of obviousness-type double patenting was intended to prevent applicants from claiming “a slight variant” of the originally-issued claims.<sup>42</sup>

The ‘049 patent has eight claims. Claim 1 recites “[a] medical device for applying compressive pressures against a patient’s limb extremity” including an “inflatable bag” to fit on the limb extremity and an “electrically powered fluid compressor for providing . . . pressurized air and a reservoir for storing pressurizing air from said compressor.” The compressor includes “a housing, a piston mounted in said housing for drawing air into and forcing air out of said housing, and an exhaust valve assembly mounted on said piston.” The compressor further includes an “exhaust filter . . . disposed so that the air pressurized by said compressor must pass through said exhaust filter before passing through said exhaust valve.” None of the other

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<sup>40</sup> *Geneva Pharms., Inc.*, 349 F.3d at 1378 n.1.

<sup>41</sup> The undersigned was unable to find any authority elaborating on the Federal Circuit’s remark that inquiries into motivation and objective criteria are not required for nonstatutory double patenting analysis.

<sup>42</sup> *Geneva Pharms., Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1377-78 (Fed. Cir. 2003).

limitations and elements defined by the remaining claims are relevant to the claims of the instant application.

**1. Claims 1, 10, and 17 are patentable over claims 1-8 of the '049 patent.**

Claim 10 recites two elements that are not recited by claims 1-8 of the '049 patent, including "a dressing for applying a negative pressure to the heel or metatarsal head regions of a foot" and "a control circuit for shutting off said compressor when said target pressure is reached."<sup>43</sup> Claims 1 and 17 recite the same or more narrow expressions of these elements.

These additional elements are not "slight variations" of the invention defined by claims 1-8 of the '049 patent. Nor is there any motivation, teaching or suggestion in Argenta et al. or Jacobs et al. for so modifying the previously claimed invention. Even if the "combination" is valid, the combination as a whole does not suggest the claimed subject matter. Claims 1-8 of the '049 patent, Argenta et al., and Jacobs et al. in no way disclose, teach, suggest, or motivate "a control circuit for shutting off said compressor when said target pressure is reached." Therefore, claims 1, 10, and 17 are patentable over claims 1-8 of the '049 patent.

**2. Claim 17 is patentable over claims 1-8 of the '049 patent.**

Claim 17 recites six elements not recited by claims 1-8 of the '049 patent.<sup>44</sup> These additional elements are not "slight variations" of the invention defined by claims 1-8 of the '049 patent.<sup>45</sup> Accordingly, claim 17 is patentable over claims 1-8 of the '049 patent.

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<sup>43</sup> The specification of the '049 patent does teach a "switching mechanism ... adapted to turn the compressor on when the pressure in the reservoir drops to a desired low pressure level or below that low pressure level" and "to turn the compressor off when the pressure in the reservoir reaches or exceeds a desired high pressure level." Col. 2, lines 15-25. But this element is nowhere suggested by the *claims* of the '049 patent. And "[i]n considering the question" of obviousness-type double patenting, "the patent disclosure may not be used as prior art." *In re Vogel*, 422 F.2d 438, 441 (C.C.P.A. 1970).

<sup>44</sup> These elements are: (1) a wound dressing for introduction of negative or subatmospheric pressure over a foot wound; (2) wherein the wound dressing comprises porous foam positioned within the foot ulcer, (3) a drape for covering and sealing the foam within said foot ulcer, and (4) a fluid communications means in fluid communication with said foam; (5) a negative pressure source for supplying subatmospheric pressure to said wound dressing



**3. Claim 1 is patentable over claims 1-8 of the '049 patent.**

Claim 1 recites seven elements not recited by claims 1-8 of the '049 patent.<sup>46</sup> These additional elements are not "slight variations" of the invention defined by claims 1-8 of the '049 patent.<sup>47</sup> Accordingly, claim 1 is patentable over claims 1-8 of the '049 patent.

**4. Claim 5 is patentable over claims 1-8 of the '049 patent.**

Claim 5 recites seven elements not recited by claims 1-8 of the '049 patent.<sup>48</sup> These additional elements are not "slight variations" of the invention defined by claims 1-8 of the '049 patent.<sup>49</sup> Claims 1-8 of the '049 patent elaborately describe the mechanical composition of an electrically powered fluid compressor, including a piston do draw air into the housing. It does not describe a *suction* pump, as claimed. Therefore, claim 5 is patentable over claims 1-8 of the '049 patent.

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through said fluid communication means; and (6) a control circuit for shutting off said compressor when said target pressure is reached.

<sup>45</sup> Furthermore, there is no motivation, teaching or suggestion in Argenta et al. or Jacobs et al. for so extensively modifying the previously claimed invention.

<sup>46</sup> These elements are: (1) a wound dressing for introduction of negative or subatmospheric pressure over a foot wound; (2) wherein the wound dressing comprises porous foam positioned within the foot ulcer, (3) a drape for covering and sealing the foam within said foot ulcer, and (4) a fluid communications means in fluid communication with said foam; (5) a negative pressure source for supplying subatmospheric pressure to said wound dressing through said fluid communication means; (6) a control circuit for shutting off said compressor when said target pressure is reached; (7) wherein the control circuit also releases air into the inflatable bladder "concurrent with the introduction of negative pressure" into the wound dressing.

<sup>47</sup> Furthermore, there is no motivation, teaching or suggestion in Argenta et al. or Jacobs et al. for so extensively modifying the previously claimed invention.

<sup>48</sup> These elements are: (1) a wound dressing for introduction of subatmospheric pressure over a foot wound; (2) wherein the wound dressing comprises porous foam positioned within the foot ulcer, (3) a drape for covering and sealing the foam within said foot ulcer, and (4) a fluid communications means in fluid communication with said foam; (5) a *suction pump* for supplying subatmospheric pressure to said wound dressing through said fluid communication means; (6) a control circuit for shutting off said compressor when said target pressure is reached; (7) wherein the control circuit also releases air into the inflatable bladder "concurrent with the introduction of negative pressure" into the wound dressing.

<sup>49</sup> Furthermore, there is no motivation, teaching or suggestion in Argenta et al. or Jacobs et al. for such an extensive modification of the previously claimed invention so that it would include a suction pump *and* a negative pressure. would dressing with porous foam and drape *and* a control circuit that releases air into the inflatable bladder "concurrent with the introduction of negative pressure" into the wound dressing.

**4. Claim 9 is patentable over claims 1-8 of the '049 patent.**

Claim 9 recites seven elements not recited by claims 1-8 of the '049 patent.<sup>50</sup> These additional elements are not "slight variations" of the invention defined by claims 1-8 of the '049 patent.<sup>51</sup> Therefore, claim 14 is patentable over claims 1-8 of the '049 patent.

**5. Claim 14 is patentable over claims 1-8 of the '049 patent.**

Claim 14 recites eight elements not recited by claims 1-8 of the '049 patent.<sup>52</sup> These additional elements are not "slight variations" of the invention defined by claims 1-8 of the '049 patent.<sup>53</sup> Even if this double patenting "combination" is valid, the combination as a whole does not suggest the claimed subject matter. Claims 1-8 of the '049 patent, the Jacobs et al. reference, and the Argenta et al. reference in no way teach or suggest the use of intermittent compression. Therefore, claim 14 is patentable over claims 1-8 of the '049 patent.

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<sup>50</sup> These elements are: (1) a wound dressing for introduction of negative or subatmospheric pressure over a foot wound; (2) wherein the wound dressing comprises porous foam positioned within the foot ulcer, (3) a drape for covering and sealing the foam within said foot ulcer, and (4) a fluid communications means in fluid communication with said foam; (5) a "single integrated compressor and vacuum pump unit" including a *suction pump* for supplying subatmospheric pressure to said wound dressing through said fluid communication means; (6) a control circuit for shutting off said compressor when said target pressure is reached; (7) wherein the control circuit also releases air into the inflatable bladder "concurrent with the introduction of negative pressure" into the wound dressing.

<sup>51</sup> Claims 1-8 of the '049 patent elaborately describe the mechanical composition of an electrically powered fluid compressor, including a piston do draw air into the housing. It does not describe a *suction pump*, much less a "single integrated compressor and vacuum pump unit." Furthermore, there is no motivation, teaching or suggestion in Argenta et al. or Jacobs et al. for so extensively modifying the previously claimed invention so that it includes a suction pump *and* a negative pressure would dressing with porous foam and drape *and* a control circuit that releases air into the inflatable bladder "concurrent with the introduction of negative pressure" into the wound dressing.

<sup>52</sup> These elements are: (1) a wound dressing for introduction of negative or subatmospheric pressure over a foot wound; (2) wherein the wound dressing comprises porous foam positioned within the foot ulcer, (3) a drape for covering and sealing the foam within said foot ulcer, and (4) a fluid communications means in fluid communication with said foam; (5) a negative pressure source for supplying subatmospheric pressure to said wound dressing through said fluid communication means; (6) a positive pressure source that is operable to supply compressive force *intermittently*; and (7) a control circuit for shutting off said compressor when said target pressure is reached; (8) wherein the control circuit also releases air into the inflatable bladder "concurrent with the introduction of negative pressure" into the wound dressing.

<sup>53</sup> Furthermore, there is no motivation, teaching or suggestion in Argenta et al. or Jacobs et al. for so extensively modifying the previously claimed invention.

**6. Claim 16 is not an obvious or slight variation of claims 1-8 of the '049 patent.**

Claim 16 recites eight elements not recited by claims 1-8 of the '049 patent.<sup>54</sup> These additional elements are not "slight variations" of the invention defined by claims 1-8 of the '049 patent.<sup>55</sup> Therefore, claim 16 is patentable over claims 1-16 of the '049 patent.

**G. Claim 7 is patentable over claims 1-8 of the '049 patent in view of Argenta et al. and Jacobs et al., and in further view of Khouri.**

The Examiner rejected claim 7 as invalid for obviousness-type double patenting over the '049 patent in view of Argenta et al. and Jacobs et al., and further in view of Khouri. This rejection is erroneous for several reasons. First, for all of the reasons set forth in part F, the Examiner's double-patenting rejection of this dependent claim cannot be sustained on the merits. Second, the Examiner strayed from the boundaries of obviousness-type double patenting analysis by arguing that "Tumey already teaches a pressure sensor 47 for regulating the inflation pressure." It may well be true that the '049 patent's *specification* teaches a pressure sensor 47 – *but that teaching is not available as prior art in an obviousness-type double patenting rejection.*<sup>56</sup> It is not mentioned in any of the '049 patent's eight claims.

Third, the Examiner cited Khouri's organ-tissue enlargement reference "to teach the convention of a pressure sensor 24 in the vacuum environment and wound dressing figure 6."

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<sup>54</sup> These elements are: (1) a wound dressing for introduction of negative pressure over a foot wound; (2) wherein the wound dressing comprises porous foam positioned within the foot ulcer, (3) a drape for covering and sealing the foam within said foot ulcer, and (4) a fluid communications means in fluid communication with said foam; (5) a negative pressure source for supplying subatmospheric pressure to said wound dressing through said fluid communication means; (6) wherein the negative pressure source is operable to supply the subatmospheric pressure intermittently; (7) a control circuit for shutting off said compressor when said target pressure is reached; (8) wherein the control circuit also releases air into the inflatable bladder "concurrent with the introduction of negative pressure" into the wound dressing.

<sup>55</sup> Nor is there any motivation, teaching or suggestion in Argenta et al. or Jacobs et al. for so extensively modifying the previously claimed invention.

<sup>56</sup> See *General Foods Corp. v. Studiengesellschaft Kohle mbH*, 972 F.2d 1272, 1281 (Fed. Cir. 1992) ("[I]n considering obviousness-type double patenting, 'the patent disclosure may not be used as prior art.'" (citing *In re Vogel*, 422 F.2d 438, 442 (CCPA 1970)).

The Examiner reasoned that “[i]t would have been obvious to one of ordinary skill in the art to further modify Tumey to include a vacuum pressure sensor as taught by Khouri to maintain proper pressure within the application site.”<sup>57</sup> But the combination of ‘049 with claims 1-8 of the ‘049 patent fails for rationales equivalent to those set forth in section C-2, discussing the Khouri reference. Namely, the Examiner’s combination assumes that a person of ordinary skill in the art would pick and choose from the Argenta et al. and Khouri references to very dramatically modify the invention set forth in claims 1-8 of the ‘049 patent. This is impermissible hindsight.

Fourth, claim 7 is not a mere “slight variation” of the invention defined by claims 1-8 of the ‘049 patent. Claim 7 recites *ten elements* not recited by claims 1-8 of the ‘049 patent.<sup>58</sup> For example, claims 1-8 of the ‘049 patent elaborately describe the mechanical composition of an electrically powered fluid compressor, including a piston to draw air into the housing. It does not describe a *suction pump*. There is no motivation, teaching or suggestion in Argenta et al. or Jacobs et al. to so extensively modify the previously claimed invention so that it includes a suction pump *and* a subatmospheric pressure wound dressing with porous foam and drape *and* a vacuum sensor *and* a control circuit with a feedback mechanism for controlling the subatmospheric pressure in the wound dressing *and* that releases air into the inflatable bladder

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<sup>57</sup> Final Office Action, at 5.

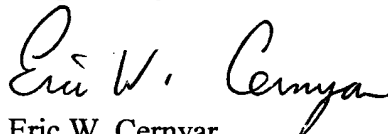
<sup>58</sup> These include: (1) a wound dressing for introduction of negative or subatmospheric pressure over a foot wound; (2) wherein the wound dressing comprises porous foam positioned within the foot ulcer, (3) a drape for covering and sealing the foam within said foot ulcer, and (4) a fluid communications means in fluid communication with said foam; (5) a *suction pump* for supplying subatmospheric pressure to said wound dressing through said fluid communication means; (6) a vacuum sensor for measuring the negative pressure supplied to the wound dressing; (7) a feedback mechanism for controlling, responsive to the measured subatmospheric pressure, the suction pump; (8) a control circuit for shutting off said compressor when said target pressure is reached and for (9) defining the subatmospheric application of pressure to said wound dressing and the positive application of force to said foot wrap; (10) wherein the control circuit also releases air into the inflatable bladder “concurrent with the introduction of negative pressure” into the wound dressing.

"concurrent with the introduction of negative pressure" into the wound dressing. This double patenting rejection is simply indefensible. Claim 7 is patentable over claims 1-8 of the '049 patent.

### **VIII. Conclusion**

Appellants have shown that the prior art lacks any teaching, suggestion or motivation to make the claimed combinations. For the foregoing reasons, Appellants believe that the Examiner's rejections of Claims 1-17 were erroneous, and reversal of the decision is respectfully requested.

Respectfully submitted,

A handwritten signature in cursive script, reading "Eric W. Cernyar".

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## APPENDIX

1. A medical apparatus for therapeutic treatment of foot ulcers, comprising:

a wound dressing for introduction of a negative pressure over a first region of a patient's foot including a wound; wherein said wound dressing is comprised of a porous foam positioned within said foot ulcer, a drape for covering and sealing said foam within said foot ulcer, and a fluid communication means in fluid communication with said foam;

a foot wrap having an inflatable bladder for applying a compressive force over a second region of said patient's foot, concurrent with the introduction of said negative pressure, to compress the veins of said patient's foot and thereby partially empty said veins;

a negative pressure source for supplying negative pressure to said wound dressing through said fluid communication means; and

a positive pressure source for supplying compressive force to said foot wrap; wherein said positive pressure source is comprised of a compressor for filling a reservoir to a target pressure, a control circuit for shutting off said compressor when said target pressure is reached and releasing said air into said inflatable bladder until an equilibrium pressure is reached between said reservoir and said inflatable bladder.

2. The medical apparatus of claim 1, wherein at least some part of said foot wrap overlaps at least some part of said wound dressing such that at least a portion of said second region overlaps said first region.

3. The medical apparatus of claim 1, wherein at least some part of said foot wrap overlaps at least some part of said wound dressing such that at least a portion of said second region overlaps said wound.

4. The medical apparatus of claim 1, wherein:  
at least a portion of said wound dressing comprises elastically compressible foam overlapping said wound; and  
at least some part of said foot wrap overlaps at least some part of said wound dressing such that said second region overlaps said foam.

5. The medical apparatus of claim 1, wherein:  
said negative pressure source comprises a suction pump; and  
said positive pressure source comprises a ventable source of pressurized gas.

6. The medical apparatus of claim 5, further comprising a control system for defining the negative application of pressure to said wound dressing and the positive application of force to said foot wrap.

7. The medical apparatus of claim 6, wherein said negative application of pressure aspect of said control system comprises:

a vacuum sensor for measuring the negative pressure supplied to said wound dressing;  
and

a first feedback mechanism for controlling, responsive to said measured negative pressure, said suction pump.

8. The medical apparatus of claim 6, wherein said positive application of pressure aspect of said control system comprises:

a pressure transducer for measuring the positive force supplied to said foot wrap; and

a second feedback mechanism for controlling, responsive to said measured positive force, the venting of said source or pressurized gas into said foot wrap.

9. The medical apparatus of claim 6, wherein:

said suction pump and said ventable source of pressurized gas comprise a single integrated compressor and vacuum pump unit; and

said control system controls said integrated compressor and vacuum pump unit responsive to both negative pressure supplied to said wound and positive force supplied to said foot wrap.

10. An apparatus for treatment of ulcers located on the heel or metatarsal head regions of a foot, comprising:

a dressing for applying a negative pressure to the heel or metatarsal head regions of a foot; and

a compressive element for applying a positive compressive force to a compressible regions of the foot including the plantar arch region; wherein said compressive element is comprised of a compressor for filling a reservoir to a target pressure, a control circuit for shutting



off said compressor when said target pressure is reached and releasing said air into said compressible regions until an equilibrium pressure is reached between said reservoir and said compressible region.

11. The medical apparatus of claim 1, wherein at least some portion of said foot wrap is operable to overlap at least some part of said wound dressing wherein at least a portion of said second region overlaps said first region.

12. The medical apparatus of claim 1, wherein at least some part of said foot wrap is operable to overlap at least some part of said wound dressing wherein at least a portion of said second region overlaps said wound.

13. The medical apparatus of claim 1, wherein:  
at least a portion of said wound dressing comprises elastically compressible foam overlapping said wound; and

at least some part of said foot wrap is operable to overlap at least some part of said wound dressing such that said second region overlaps said foam.

14. The medical apparatus of claim 1, wherein the positive pressure source is operable to supply said compressive force intermittently.

15. The medical apparatus of claim 1, wherein the positive pressure source comprises an oscillating air compressor.

16. The medical apparatus of claim 1, wherein the negative pressure source is operable to supply said negative pressure intermittently.

17. A medical apparatus for therapeutic treatment of foot ulcers, comprising:

a wound dressing for introduction of a negative pressure over a first region of a patient's foot including a wound, wherein said wound dressing is comprised of a porous foam positioned within said foot ulcer, a drape for covering and sealing said foam within said foot ulcer, and a fluid communication means in fluid communication with said foam;

a foot wrap having an inflatable bladder for applying a compressive force over a second region of the patient's foot, the second region at least partially overlapping the first region;

a negative pressure source that supplies negative pressure to the wound dressing through said fluid communication means; and

a positive pressure source that supplies compressive force to the foot wrap; wherein said positive pressure source is comprised of a compressor for filling a reservoir to a target pressure, a control circuit for shutting off said compressor when said target pressure is reached and releasing said air into said inflatable bladder until an equilibrium pressure is reached between said reservoir and said inflatable bladder.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

Ex Parte RICHARD C. VOGEL, DAVID M. TUMEY,  
SUSAN P. MORRIS, and L. TAB RANDOLPH

Appeal No. 2004-\_\_\_\_\_  
Application No. 09/458,280

**EXHIBITS TO APPELLANTS' BRIEF**

<b>Reference .....</b>	<b>Exhibit Number</b>
U.S. Patent No. 5,489,259 to Jacobs et al .....	1
U.S. Patent No. 5,645,081 to Argenta et al .....	2
U.S. Patent No. 5,007,411 to Dye .....	3
U.S. Patent No. 5,443,440 to Tumey et al. ....	4
U.S. Patent No. 5,701,917 to Khouri .....	5
U.S. Patent No. 5,840,049 to Tumey et al. ....	6
Article from ANNALS OF PLASTIC SURGERY .....	7
Excerpts from MOSBY'S MEDICAL, NURSING & ALLIED HEALTH DICTIONARY (4 <sup>th</sup> ed) .....	8
Excerpt from MERRIAN-WEBSTER'S COLLEGIATE DICTIONARY (10 <sup>th</sup> ed). ....	9
Excerpt from MICROSOFT'S ENCARTA COLLEGE DICTIONARY .....	10
Excerpts from WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY .....	11
U.S. Patent No. 4,829,995 to Metters .....	12
U.S. Patent No. 5,003,971 to Buckley .....	13
U.S. Patent No. 5,792,088 to Felder et al. ....	14
Article from JOURNAL OF SURGERY, GYNECOLOGY & OBSTETRICS .....	15

## Vacuum-Assisted Closure: A New Method for Wound Control and Treatment: Clinical Experience

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Despite numerous advances, chronic and other difficult-to-manage wounds continue to be a treatment challenge. Presented is a new subatmospheric pressure technique: vacuum-assisted closure (The V.A.C.). The V.A.C. technique entails placing an open-cell foam dressing into the wound cavity and applying a controlled subatmospheric pressure (125 mmHg below ambient pressure). Three hundred wounds were treated: 175 chronic wounds, 94 subacute wounds, and 31 acute wounds. Two hundred ninety-six wounds responded favorably to subatmospheric pressure treatment, with an increased rate of granulation tissue formation. Wounds were treated until completely closed, were covered with a split-thickness skin graft, or a flap was rotated into the healthy, granulating wound bed. The technique removes chronic edema, leading to increased localized blood flow, and the applied forces result in the enhanced formation of granulation tissue. Vacuum-assisted closure is an extremely efficacious modality for treating chronic and difficult wounds.

Argenta LC, Morykwas MJ. Vacuum-assisted closure: a new method for wound control and treatment: clinical experience. *Ann Plast Surg* 1997; 38:563-577

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The management and treatment of difficult wounds have been seminal forces that led to the development of plastic and reconstructive surgery as a specialty. Despite many recent advances in the basic science of wound healing, physicians continue to practice clinically within very well-defined paradigms. For more than 5,000 years, surgeons have used sutures to apply force to adjacent viable tissue at the wound edges to bring about edge apposition and subsequent healing by primary intention [1]. Contaminated wounds and wounds with questionable tissue viability led to the development of delayed, primary intention healing wherein the wound was left open for a finite period of time, theoretically decontaminated, and then sutured closed. When trauma or

surgery resulted in significant losses of tissue, making apposition of the edges of the wound physically impossible, surgical intervention in the form of flaps and skin grafts evolved as the wound treatment of choice. When wounds failed to heal or patients were too debilitated for surgical closure, healing by secondary intention, by packing or prolonged application of dressings until the wound hopefully closed and epithelialization occurred, became the treatment of choice.

In the past 25 years, we have entered an era where patients are living longer with more complex systemic pathology and are subjected to more extensive surgical treatment procedures. The number of patients with chronic, nonhealing wounds and wound complications continues to increase, stressing physician, hospital, and economic resources. In this population, the aim oftentimes becomes not closure, but control of the wound to maximize patient comfort, minimize complications, increase survival, as well as to control cost and hospitalization time.

We present in this paper a new method of treatment using subatmospheric pressure that can be applied to a wide variety of acute, subacute, or chronic wounds. This publication reports the first 300 human wounds treated in our clinical trial that led to the development of the vacuum-assisted wound closure technique and device. (The vacuum-assisted wound closure device and technology [The V.A.C.] are subject to pending United States and international patents and applications assigned to Wake Forest University. A worldwide license has been assigned to Kinetic Concepts, Inc., San Antonio, TX. The V.A.C. is a trademark of Kinetic Concepts, Inc.) The technique of vacuum-assisted closure was devised to facilitate wound treatment for a wide range of wounds with the aim of increasing patient comfort, decreasing patient morbidity, decreasing cost, and decreasing the length of hospitalization. The technique can be used as

adjunctive therapy before or after surgery, or as an alternative to surgery in a debilitated patient.

## Materials and Methods.

### The Device

The subatmospheric pressure system employs a medical-grade reticulated polyurethane ether foam dressing that has been cleared by the Food and Drug Administration for wound tissue contact. The 400- to 600- $\mu$ m pore size of the foam maximizes potential tissue ingrowth [2, 3]. Embedded in the foam dressing is a noncollapsible evacuation tube. Side ports in the tube allow communication of the lumen of the tube to spaces in the reticulated foam, while the open-cell nature of the foam ensures equal distribution of the applied subatmospheric pressure force to every surface of the wound in contact with the foam.

The sterile foam dressing is trimmed at the bedside to the appropriate size and geometry for each individual wound. The foam dressing is placed into the wound defect, allowing the evacuation tube to exit parallel to the skin surface. In very large wounds, multiple foam dressings are placed in contact with one another. Provided that surfaces of the foam dressing are allowed contact with one another, the subatmospheric pressure transmitted to one foam is equally transmitted to all contiguous foam dressings. The surface of the wound containing the foam dressing is covered with an adhesive drape extending 5 cm beyond the margins of the wound over adjacent intact skin to create an airtight seal. The open wound is thus converted into a controlled closed wound. The evacuation tube is situated to avoid bony prominences so that it does not become a pressure point on adjoining areas of the patient. The proximal end of the evacuation tube leads to a remote collection canister into which the effluent from the wound is drawn when subatmospheric pressure is applied. In the commercially available unit, appropriate sensing devices are incorporated into the collection canister so that warnings are sounded when the canister is filled, thus avoiding uncontrolled, excessively rapid fluid, or potentially blood, egress. The collection canister is in turn connected to an adjustable vacuum pump. The magnitude of the vacuum and

whether the vacuum application is continuous or intermittent can be adjusted.

### Wound Classification and Treatment Regime

The first 300 wounds treated with subatmospheric pressure therapy (The V.A.C.) have been arbitrarily assigned to one of three categories for the purposes of discussion: (1) chronic wounds (pressure ulcers, stasis ulcers, etc.;  $N = 175$ ), arbitrarily defined as wounds that had been open for more than 1 week and exhibited no progress toward normal wound healing; (2) subacute wounds (infected and dehiscent wounds, avulsions, open amputations;  $N = 94$ ), defined as wounds that had been open for less than 7 days, but more than 12 hours; and (3) acute wounds (acute avulsions, evacuated hematomas, gunshot wounds, eviscerations, etc.;  $N = 31$ ), defined as wounds that had been open less than 12 hours. Wounds in this study were treated until completely healed, until the patient and wound progressed to a point where a lesser surgical procedure could be performed to close the wound, until the patient refused further treatment, or until the patient expired.

Patients were treated in accordance with the institutional review board policies of Bowman Gray School of Medicine, Wake Forest University. The first 50 patients in this series were hospitalized for the duration of their treatment with careful monitoring of wound healing, infection, hemodynamic stability, electrolyte balance, and patient comfort. Initial studies were conducted using continuous application of 125 mmHg of subatmospheric pressure. Subsequent studies revealed the rate of wound closure could be expedited by cycling the application of subatmospheric pressure at 5-minutes-on/2-minutes-off intervals. The first 100 patients were treated by the senior author and the resident staff under his direct supervision. Subsequently, clinical faculty, residents under clinical faculty direction, physicians' assistants, and ward nurses on the surgical service were trained in the use of this device and assisted in the treatment and management of these patients. In addition, outpatient nurses, physicians in areas adjacent to the hospital, and oftentimes the patients themselves or their family members were trained to change the device and care for the wound at home.

### Practical Considerations

The sine qua non of all wound healing is the removal of all nonviable tissue prior to instituting therapy. This is paramount, as nonviable tissue becomes a focus for bacterial proliferation and a source of lytic enzymes, bacterial toxins, and other factors that impede wound healing. All nonviable tissue is debrided in the operating room, in the clinic, or at the bedside, depending on the needs of the particular patient. Debridement was performed with cold knife, electrocautery, or carbon dioxide laser, and meticulous hemostasis was achieved following debridement. In patients in whom the extent of necrosis cannot be completely determined, the patient should be redebrided at 24-hour intervals until all nonviable tissue is removed.

It is imperative that the foam dressing be placed into direct contact with the deepest surface of the wound. This is particularly important when bone or orthopedic hardware is present in the wound. If cortical surfaces of bone are exposed, it is helpful to remove the cortex to encourage granulation tissue formation. When major vessels are exposed, transposition of local tissues or muscle flaps over the vessel should be attempted. Mesh may be used if the integrity of the abdominal wall has been disrupted. Omentum should be placed between the viscera and mesh whenever possible.

Obtaining an adequate airtight seal may be difficult in wounds adjacent to the anus or vagina, or when adjacent tissue is moist, as in avulsions or burns. Duoderm (Convatec; Princeton, NJ) applied to the moist area or over the anus or vagina is useful in obtaining a seal. The adhesive drape is applied directly over the Duoderm.

Dressings are changed at 48-hour intervals and may be performed at the bedside as a clean, but not necessarily as a sterile, procedure. Since the wound is a controlled open wound, sterility has not been necessary. The foam dressing is provided sterile, but we have routinely used only clean gloves and clean instruments for trimming and placing the device. In massive wounds, this change is usually performed in the operating room or in the intensive care unit with appropriate sedation. Patients who required pain medication for gauze dressing changes normally require medication for The V.A.C. dressing changes. Pain

associated with collapse of the dressing usually subsided after 20 to 30 minutes. Continuous subatmospheric pressure rather than cyclical application may decrease pain in these patients.

When dressings are changed, patients are allowed to shower and bathe as desired. While the wounds should be exposed to subatmospheric pressure as much as possible to facilitate wound closure, patients may disconnect themselves from the vacuum source as needed. Patients are allowed to ambulate and often return to work or school. Our present regimen allows treatment of many wounds on an outpatient basis with the patient returning to the clinic at intervals of 2 to 3 weeks for monitoring.

Depending on the size, location, and duration of the wound, significant volumes of fluid may be removed in the first several days of treatment. Patients with massive wounds or those hemodynamically compromised are kept in the intensive or intermediate care unit, allowing simultaneous monitoring of systemic hemodynamics and electrolyte balance. Large volumes of fluid may be removed in the first 24 hours in acute wounds, burns, and crush injuries. Our studies indicate, however, that with monitoring of urine output and hemodynamic stability, excessive fluid replacements are not necessary to ensure homeostasis. Despite using this treatment in many extremely debilitated patients, we have observed no significant changes in electrolyte balance, renal or hepatic function, or other systemic effects. Exposed malignancy has been the only empirical contraindication to treatment with The V.A.C. Anticoagulated patients may be treated but should be monitored carefully.

A large number of wounds have been treated with split-thickness skin grafts, and The V.A.C. technique used to secure the graft in place. Once an adequate granulating bed was achieved, a split-thickness skin graft of 12 one-thousandths of an inch was meshed one to one and secured in place with staples to the recipient site. A single layer of nonadhesive dressing such as Xeroform (Sherwood Medical, St. Louis, MO) was placed over the skin graft and below the foam dressing. A continuous subatmospheric pressure of 50 to 75 mmHg was applied to the wound for 4 days. Any transudate from the wound was able to egress through the meshed graft and was removed

from the site. This technique allowed uniform, firm application of pressure to the skin graft and at the same time minimized shear forces that may have impaired adhesion and vascularization of the graft. Patients were immobilized as much as possible, but were allowed to ambulate to toilet facilities or about their rooms.

Four days after grafting, the foam dressing was removed and the graft examined. If complete or almost-complete take was not observed, an additional small amount of graft that had been harvested at the initial operation and kept in culture was applied to the nonviable areas and the foam dressing was replaced for an additional 3 days. This practice obviated an additional trip to the operating room. With this regimen more than 90% of these wounds were grafted successfully on the first surgical attempt. Granulation tissue that occasionally exuded through the mesh interstices was treated with one to two applications of silver nitrate.

### Chronic Wounds

Chronic wounds are defined in this study as wounds that had been open and showed no progress toward healing for a minimum of 1 week. The vast majority of cases were open for longer periods of time. One hundred seventy-five wounds were treated in this category and included pressure ulcers, long-term dehiscence wounds, venous stasis ulcers, radiation ulcers, vasculitic and diabetic ulcers, and a wide variety of miscellaneous long-standing wounds. Many of these patients were either debilitated, nonsurgical candidates or individuals who had failed multiple surgical procedures in the past. Six patients in this group expired of concomitant disease during therapy. Independent examination of these patients' records revealed that there was no contribution of subatmospheric pressure therapy to their cause of death.

Initial treatment consisted of inpatient or outpatient surgical debridement of all nonviable tissue. Once hemostasis was obtained, the foam dressing was applied directly to the debrided wound and treatment begun immediately. Subatmospheric pressure was applied in a continuous mode for the first 48 hours, during which variable amounts of edematous fluid was removed from most wounds.

Following the first 48 hours of therapy, patients were begun on intermittent therapy, using a 5-minutes-on/2-minutes-off cycle. The device was changed at 48-hour intervals. At the time of dressing changes, the patients were treated with hydrotherapy, usually bedside pulsatile irrigation, as necessary. Most mobile patients were allowed to move about at will without specific restrictions. Therapy was continued until the wound was completely healed, until the wound had decreased significantly so that a lesser procedure such as a skin graft or local flap could be accomplished, or until the wound could be closed by delayed primary intention.

### Pressure Ulcers

A total of 141 pressure ulcers have been treated: 87 were stage III and 54 were stage IV pressure ulcers. Wounds treated included 63 sacral, 41 ischial, 26 trochanteric, and 11 in miscellaneous locations. The pressure ulcers had been present for periods of time ranging from 10 days to 3 years. The vast majority of patients had experienced no significant improvement with multiple dressing changes or topical treatments. Nineteen percent (27 of 141) of these patients were considered nonsurgical candidates because of debility or due to concomitant disease. Eighty-two patients (58%) had had previous surgical procedures performed either on the existing pressure ulcer or on an ulcer adjacent to the existing wound that compromised surgical options.

### Venous Stasis and Other Vasculitic Ulcers

Thirty-one venous stasis or other vasculitic ulcers have been treated, ranging in size from 6 to 120 cm<sup>2</sup>. Twenty-eight (90%) of these patients had failed previous medical or surgical therapy. Initial treatment required debridement to viable bleeding tissue. In smaller wounds, EMLA (Astra Pharmaceutical Products, Inc.; Westborough, MA) was placed directly in the wound for anesthesia and debridement performed in the office. The foam dressing was placed immediately after obtaining hemostasis. Patients with venous stasis ulcers may require lower initial pressures than other patients because of pain. Initially wounds were treated with 50 mmHg on a constant mode and gradually progressed as tolerated to 125 mmHg.

Unlike most wounds, venous stasis and other vasculitic ulcers responded more favorably to continuous subatmospheric pressure as opposed to cycled subatmospheric pressure. The V.A.C. dressings were changed at 48-hour intervals. Patients were kept at bedrest with their legs elevated as much as possible to facilitate removal of edematous fluid during the first several days of therapy.

Once an adequate granulating bed had been achieved, cultured keratinocytic allografts were used to enhance reepithelialization of smaller wounds. In larger wounds, a split-thickness skin graft of 12 one-thousandths of an inch was placed on the granulating bed and continuous subatmospheric pressure of 50 to 75 mmHg was applied to the wound for 4 days. Once graft take had been ensured, subatmospheric pressure therapy was discontinued and a nonadherent pressure dressing was applied to the wound. Approximately 10 days after the procedure, chronic pressure garments were measured and applied. The long-term stability of venous stasis ulcers is directly related to patients' compliance and wear of long-term pressure garments.

#### Subacute Wounds

Into this category were placed wounds that had been open for less than 7 days. Ninety-four patients have been treated in this category. Subacute wounds included 36 dehiscent wounds, 37 open wounds with exposed orthopedic hardware and/or bone, and other miscellaneous wounds. As with chronic wounds, all nonviable tissue was debrided and cultured. Hemostasis was obtained, and the V.A.C. foam dressing was placed and secured to the margins of the wound. Subatmospheric pressure therapy of 125 mmHg was applied continuously for the first 48 hours and then applied in a cyclical manner (5 minutes on/2 minutes off). Sterile foam dressings were changed at 48-hour intervals. The wounds were treated until a healthy bed of granulation tissue became evident, at which time the wound was closed primarily, a split-thickness skin graft applied, or a flap was rotated. Initially, most patients in this category were treated in the hospital. However, the vast majority of later patients were treated at home by visiting nurses. Patients were monitored in the clinic at 2- to 3-week intervals. Systemic

antibiotics were administered intravenously for prolonged periods at home when necessary, particularly when hardware or bone had been exposed.

#### Acute Wounds

This group included large soft-tissue avulsions, contaminated wounds, hematomas and abscesses that were evacuated, gunshot wounds, and eviscerations. Extensive edema and contamination of the exposed tissue characterized wounds in this category. Thirty-one patients in this category have been treated. One patient who sustained multiple gunshot wounds died of pulmonary embolism during treatment. These patients were generally in much better systemic health and had a much better nutritional status than patients in the other wound categories.

At the time of surgery, nonviable tissue was debrided and hemostasis obtained. When abdominal or thoracic viscera were exposed, omentum was placed over the viscera and absorbable Vicryl mesh was used to secure the integrity of the cavity and control evisceration. Exposed major vessels were covered with adjacent soft tissue or muscle to minimize risk of bleeding. Likewise, muscle flaps were used to cover acutely exposed lung and heart.

After adequate debridement, the foam dressing was placed directly over exposed muscle and other soft tissue. In abdominal wounds, the foam dressing was placed directly over the Vicryl mesh. If mesh could not be placed, foam dressings were placed directly over the heart, lung, liver, and spleen with no complications.

A subatmospheric pressure of 125 mmHg was applied continuously for the first 48 hours or until the amount of fluid removed every 24 hours had decreased significantly. Once the effluent stabilized, subatmospheric pressure was then applied intermittently at 5-minutes-on/2-minutes-off intervals. The dressings were changed at 48-hour intervals. For wounds that involved skin, soft tissue, or muscle degloving, and when the viability of the degloved tissue was in question, multiple incisions were made in the skin to allow egress of sequestered blood and fluid, and the V.A.C. dressing was applied directly over the degloved tissue to facilitate readhesion of the degloved tissue.



## Results

As previously discussed in the basic science paper on this study [4], a significant increase in the rate of granulation tissue formation was achieved concomitant with a decrease in the size of the wound in most cases. Measurements of the number of microorganisms per gram of tissue in contaminated wounds demonstrated a progressive decrease in bacterial count that clinically paralleled evidence of increased vascularity and the development of granulation tissue.

### Chronic Wounds

The vast majority (171 of 175) of chronic wounds responded favorably to the application of subatmospheric pressure. Removal of edema surrounding the chronic wound was followed by the production of granulation tissue. The volume of fluid removed varied directly with the size and chronicity of the wound, and the volume progressively decreased over time. Exudate volumes of up to 1,000 ml of fluid per day were safely removed from large ulcers without significant hemodynamic or biochemical imbalances:

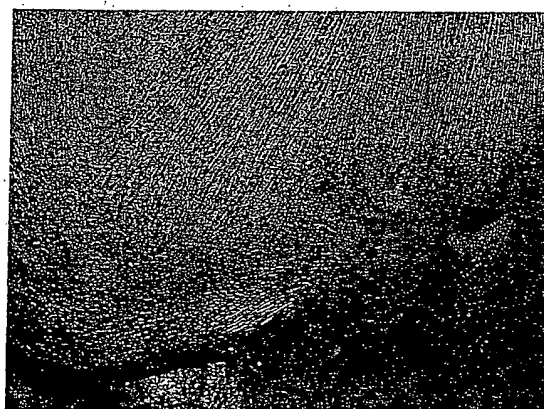
A significant decrease in the firmness of surrounding tissues, particularly in venous stasis and pressure ulcers, was observed following the first 48 hours of subatmospheric pressure therapy. Tissues that were initially indurated became much more pliable.

### Pressure Ulcers

The length of treatment of pressure ulcers varied directly with the size of the lesion. Forty-three wounds were treated for 2 weeks or less, 55 were treated for 3 to 4 weeks, 27 were treated for 5 to 10 weeks, 10 were treated for 10 to 15 weeks, and 6 were treated for 16 weeks or more. Thirty-two percent of pressure ulcers healed completely in 2 to 16 weeks. Forty-six percent of wounds closed more than 80% and were treated with skin grafts, rotation of smaller muscle flaps, primary closures, or were discharged to complete their healing with dressing changes. Fifteen percent of wounds healed 50 to 80% and were treated with skin grafts, rotation muscle flaps, or were discharged with dressing changes. Six patients died of other causes during the course of treatment. Wounds being treated on 2 of the 6 patients who



A



B

*Fig 1. (A) A 15 × 15 × 6-cm deep sacral pressure ulcer of unknown duration (pretreatment) on a 77-year-old diabetic female who was not a surgical candidate due to anesthesia risks. Following 16 weeks of treatment with The V.A.C., the wound had healed to a 5-cm diameter nonepithelialized area. Edges were undermined under local anesthesia, approximated, and sutured. The wound has been stable for 5 years. (B) Wound 7 days postclosure.*

died were responding to subatmospheric pressure therapy, while wounds on the remaining 4 patients did not respond to subatmospheric pressure treatment. To date, no pressure ulcers have recurred at the original wound site treated with The V.A.C., although pressure ulcers have recurred in other locations in some patients. Examples of pressure ulcers treated are shown in Figures 1 and 2.

### Venous Stasis and Other Vasculitic Ulcers

This difficult type of wound has responded well to subatmospheric pressure therapy. Small



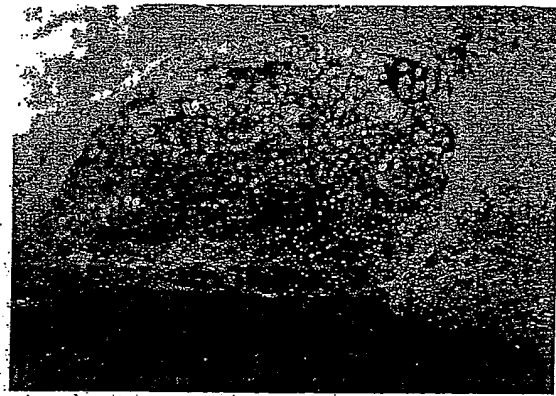
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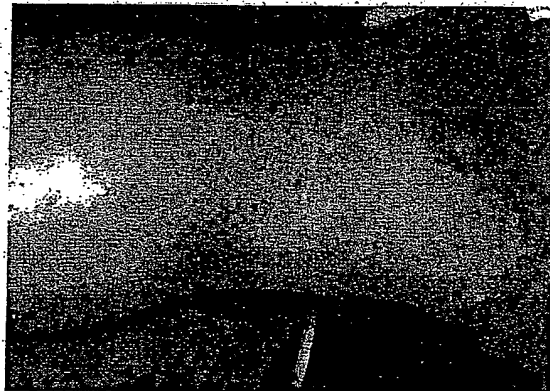
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*Fig 2. (A) A 5-cm-diameter pressure ulcer of unknown duration (pretreatment) on the right medial heel of a 77-year-old diabetic female (same patient as in Fig 1) with severe peripheral vascular disease who had her great toe amputated 4 years previously. The wound healed completely following 6 weeks of subatmospheric pressure treatment and has been stable for 5 years. (B) Wound posttreatment.*

amounts of exudate were removed from these wounds, typically 1 to 25 ml every 24 hours. Most wounds demonstrated significant reduction of edema and production of granulation tissue within 4 to 6 days despite their long-standing nature. Once a granulating bed was obtained, a split-thickness skin graft was applied and held in place with subatmospheric pressure. Ninety percent of patients with stasis ulcers treated in this manner were successfully treated with the first graft. Three patients who were noncompliant with wearing of pressure garments have suffered late recurrences of their ulcers at the margins of



A



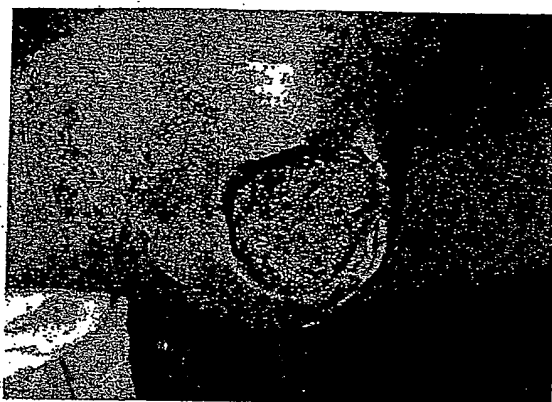
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*Fig 3. (A) A large (6 × 10-cm) venous stasis ulcer of 2.5 year duration (pretreatment) on the lower right extremity of a 75-year-old female. Two previous coverage attempts with split-thickness skin grafts had failed. Following 2 weeks of subatmospheric pressure treatment a split-thickness skin graft was placed and held in place for 4 days with The V.A.C. (B) Wound appearance 2 years postgrafting showing stability of wound site.*

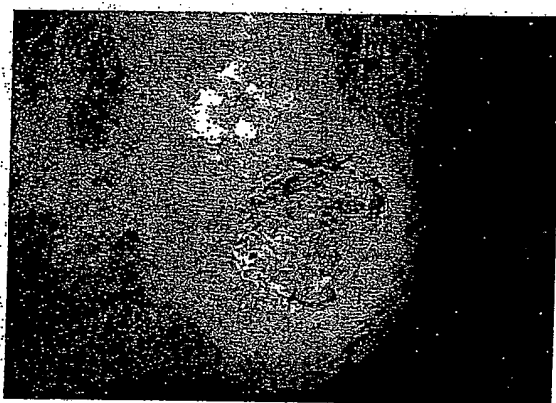
the previous graft. Representative wound responses are shown in Figures 3 and 4.

#### Subacute Wounds

Wounds in this category responded more rapidly and more uniformly than chronic wounds. The rate of granulation tissue formation and wound closure was significantly more rapid than patients with chronic wounds. The amount of fluid removed from the wound in the first days of treatment varied directly with the size of the lesion, but generally was less than pressure ulcers or acute wounds of the same size.



A



B

*Fig 4. (A) A diabetic heel ulcer (5 × 6 cm) of 7-month duration (pretreatment) on a morbidly obese, hypertensive 75-year-old patient. Following 2 weeks subatmospheric pressure treatment the wound was covered with a split-thickness skin graft. (B) Wound 6 months postgrafting.*

Thirty-seven patients with exposed orthopedic hardware or bone were treated successfully with closure of adjacent muscle and granulation tissue over the bone and hardware. Twenty-six of the 94 wounds healed completely, while the remaining 68 wounds granulated and contracted to smaller wounds that were easily controlled with split-thickness skin grafts, secondary closure, or minor flaps. Representative wounds are shown in Figures 5 and 6.

#### Acute Wounds

Patients presenting with acute soft-tissue wounds developed granulation tissue at an extremely rapid rate and healed more quickly than patients with chronic or subacute wounds. Large volumes

of edematous fluid were removed from massive soft-tissue wounds. Four liters of fluid were removed from a traumatic hip disarticulation wound site on a large patient without any changes in systemic hemodynamics. Fluid output in this patient dropped to less than 1,000 ml per day after 5 days of treatment.

The majority of patients in this group were treated until an adequate bed of healthy granulation tissue developed. The wound was then covered with a split-thickness skin graft, a flap was rotated, or the wound was closed primarily. One patient died of a pulmonary embolism during treatment. All other wounds were managed successfully and were successfully closed. Representative wounds of various causes are shown in Figures 7, 8, and 9.

#### Complications

Complications encountered using The V.A.C. therapy have been relatively few and largely technical. Erosion of adjacent tissue with the evacuation tube may occur if it is positioned directly over bone or if the patient is placed in a position such that the patient lies on the tube. This is particularly important in comatose and mentally compromised patients.

Pain requiring narcotic analgesia occasionally occurs in traumatic wounds, but it is difficult to separate how much was due to The V.A.C. device as opposed to the actual trauma. Many patients with acute wounds reported that pain associated with subatmospheric pressure therapy dissipated approximately 20 minutes after initial compression of the foam dressing, and that the foam dressing was much more comfortable than previous saline wet-gauze dressings. Stasis ulcers and chronic vasculitic lesions of the lower extremity were particularly prone to discomfort. The most efficacious treatment of these wounds is continuous application of 50 mmHg and then gradually increase the subatmospheric pressure as the patient tolerates the device.

Excessive ingrowth of granulation tissue into the foam dressing has been seen when the foam dressing has been left in place for longer than 48 hours. Removal of the dressing disrupts the newly formed capillary buds and may result in minor bleeding. This is particularly true in young patients with acute wounds. All dressings, how-

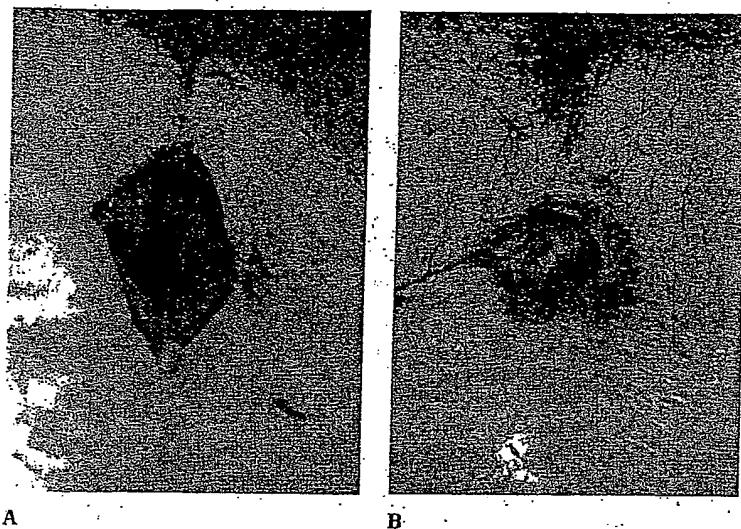


Fig 5. (A) Dehiscent sternal incision (pretreatment) on a 60-year-old male following coronary artery bypass surgery. A rectus muscle flap and right pectoralis major muscle flap had been previously rotated with hematoma, death of portions of both flaps, and wound dehiscence (4 × 5 cm). The pericardium was exposed. The wound was actively treated with subatmospheric pressure therapy (75 mmHg) on an outpatient basis for 6 weeks. (B) Eighteen months postsubatmospheric pressure treatment.

ever, could be removed without need for surgical extirpation. Rarely is electrocoagulation required; the vast majority of such bleeding is treated simply with pressure. Foam dressings should be changed at 48-hour intervals for the majority of patients, and for infants and adolescents at 24-hour intervals, particularly in acute wounds. Major bleeding from erosion of large vessels has not been encountered despite very large wounds in debilitated patients.

Of the 37 wounds treated in which there was exposed bone and/or hardware, late infection developed in 2 patients because of overgrowth of granulation tissue and adhesion of adjacent musculature over nonviable bone and 1 patient required late removal of orthopedic hardware from the wound. It is imperative that nonviable bone be debrided, since healing of the adjacent tissue may result in later loculation and sequestration. When such infection does occur, surgical debridement of the sequestrum becomes necessary.

One enteric fistula developed when a foam dressing was placed directly over compromised intestine in a debilitated patient who had eviscerated. Separation of the intestine from the V.A.C. foam dressing with a sheet of Marlex or Vicryl mesh minimizes this complication and ensures better integrity of the abdominal cavity. The rate at which granulation tissue will grow through the mesh in response to the subatmospheric pressure is substantial, oftentimes covering the mesh within a week.

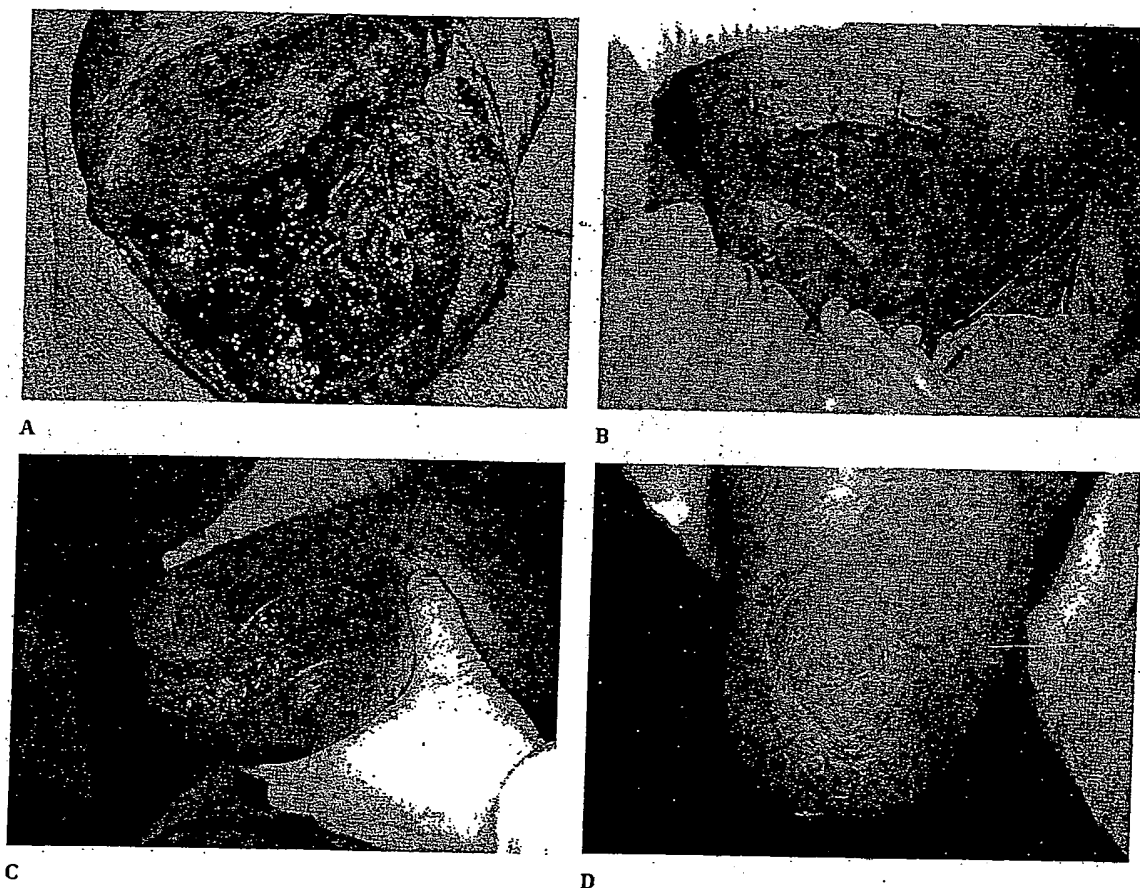
Odor may become a problem in chronic wounds during treatment. When dressings are removed at 48-hour intervals, patients who have developed odor problems should be treated with hydrotherapy and cleansed appropriately.

The application of large, uncontrolled vacuums such as wall suction in conjunction with the V.A.C. foam dressings is discouraged. Desiccation of tissue may occur when an inadequate seal has been obtained and large volumes of air are drawn across the wound surface by wall suction. Progressive necrosis of tissue may then occur.

No deaths or hospitalizations have resulted from the V.A.C. treatment. Seven patients have died in the course of treatment with the subatmospheric pressure because of other concomitant disease processes.

## Discussion

The impetus for developing the vacuum-assisted closure technique evolved from a patient with a large, infected, dehiscent wound that could not be reclosed because of the extreme debility of the patient. Faced with ever-increasing numbers of such patients with debilitating chronic wounds, the majority in the form of pressure ulcers, use of the device was initially directed toward the treatment of chronic "unsalvageable" wounds mounted, the treatment modality was applied to subacute and

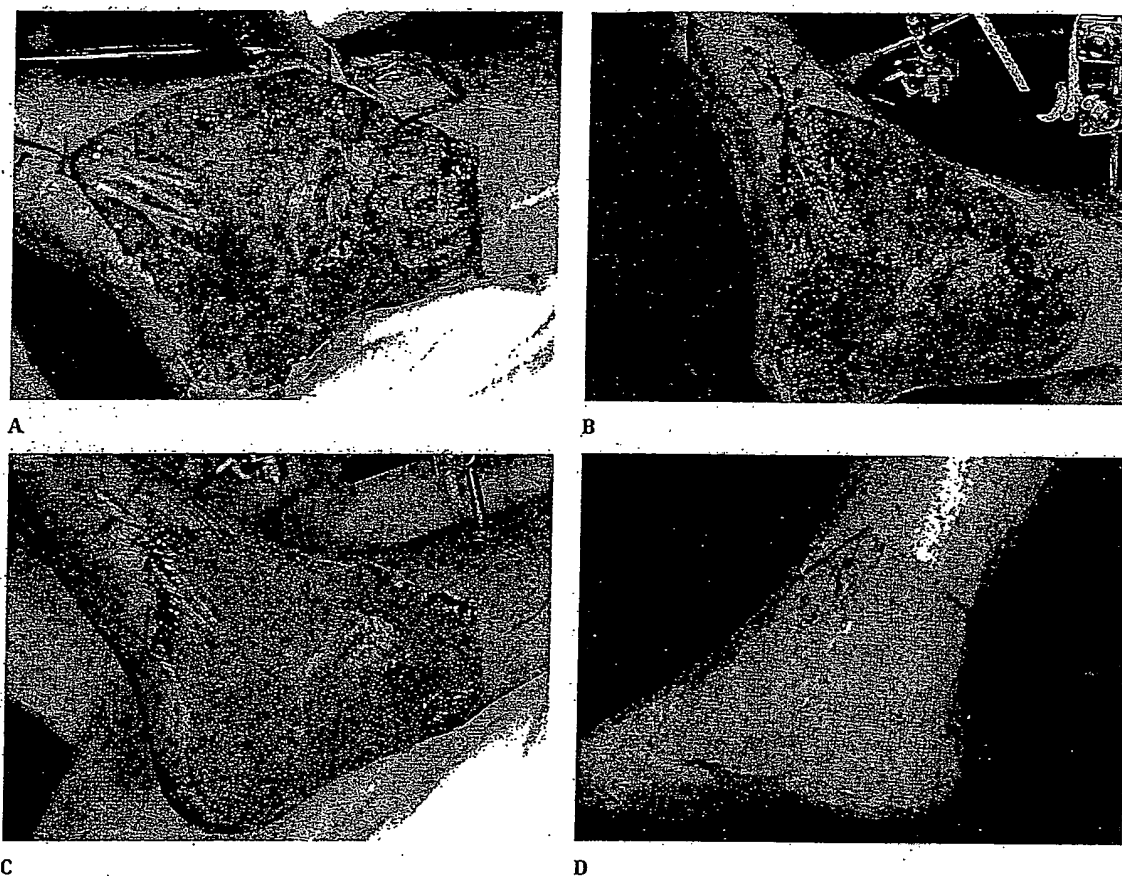


*Fig 6. (A) Dehiscent above-the-knee amputation site (five previous revisions due to chronic osteomyelitis) on the right leg of a 45-year-old female (pretreatment). The wound site was treated with The V.A.C. for 3 weeks, at which time the wound was healed. (B) Wound following 1 week of subatmospheric pressure treatment. (C) Wound following 2 weeks of subatmospheric pressure treatment. (D) Wound 1 month after cessation of subatmospheric pressure treatment.*

acute wounds. The use of subatmospheric pressure to treat complications such as dehiscence or infection has been particularly gratifying. Such complications usually prolong hospitalization and require that the patient, although frequently quite debilitated, undergo subsequent procedures. Treatment with the vacuum-assisted closure device allows many of these patients to be discharged from the hospital and treated at home on a much less costly basis than has been previously achieved.

While considerable years of research will be required to define the precise mechanism for accelerated wound treatment with The V.A.C., based on our research thus far and our clinical observations on the healing of 300 patients we postulate interrelated factors are the basis for the

success of the technique: (1) the removal of excess interstitial fluid, (2) the increase in vascularity and associated decrease of bacterial colonization, and (3) responses of the tissues around the wound to mechanical forces. Tissues surrounding chronic wounds, and to a lesser extent subacute and acute wounds, are characterized by localized collections of interstitial or third-space fluid similar to the "zone of stasis" classically described with burn injuries. The collection of third-space fluid mechanically compromises the microvasculature and lymphatic system, increasing capillary and venous afterload, and thus impedes the delivery of oxygen and nutrients as well as the egress of inhibitory factors and toxins [5, 6]. Both clinically and experimentally, the application of subatmospheric pressure removes



*Fig 7. (A) Skin and subcutaneous tissue had been traumatically excised by a lawn mower off the medial aspect of the right ankle of a 68-year-old patient exposing bone and tendons (pretreatment). A free flap was declined due to the patient's long history of smoking and atherosclerosis. The V.A.C. treatment was used for 2 weeks, then a split-thickness skin graft was placed with 95% take. Subatmospheric pressure was used for 4 days to secure the graft in place. The site has been stable for 1 year with no functional deficit. (B) Following 1 week of subatmospheric pressure treatment. (C) Following 2 weeks treatment with healthy granulating bed over tendons. (D) Wound site 6 months postgrafting.*

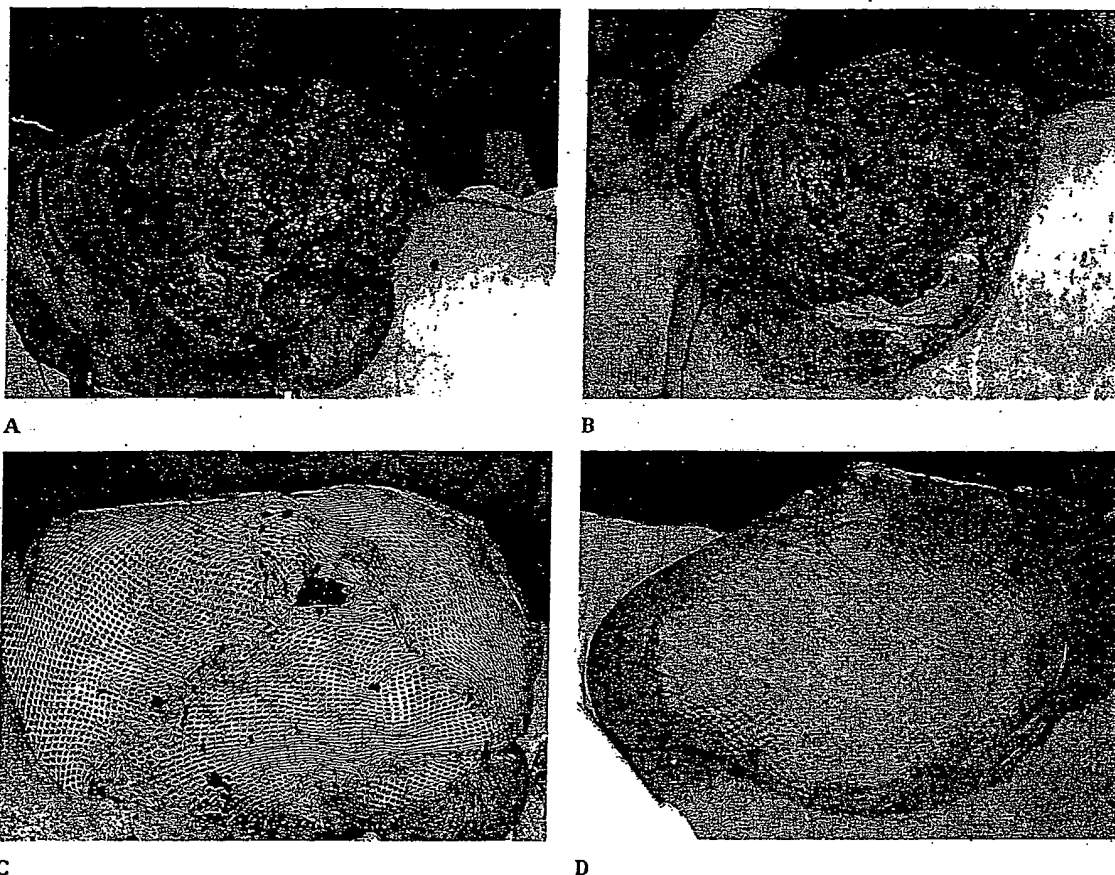
third-space fluid from the area immediately adjacent to the wound. Up to 1 l of fluid has been removed from large pressure ulcers during a 24-hour period, while 4 l were removed from a large, acute traumatic hip avulsion in the initial 24 hours.

Removal of third-space fluid results in a decrease in tissue turgor and a decrease in capillary afterload, which promotes better capillary circulation and better inflow. Laser Doppler flow studies showed a significant increase in blood flow adjacent to the wound during the course of treatment with subatmospheric pressure. The restoration and increase in vascularity encountered at

the edges of the wound are extremely striking after several foam dressing changes.

Additionally, the removal of excess chronic wound fluid is thought to remove inhibitory factors present in the fluid. Experimentally, fluids removed from chronic wounds have been found to suppress the proliferation of keratinocytes, fibroblasts, and vascular endothelial cells in vitro [7, 8]. In addition, these fluids contain elevated levels of matrix metalloproteinases such as collagenases and elastases, and their degradation products [9-12]. Studies are presently underway that examine, qualitatively and quantitatively, growth and inhibitory factors in wound





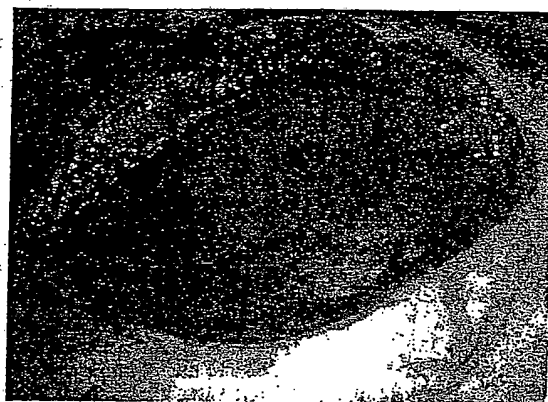
**Fig 8.** (A) Traumatic disarticulation of the left leg at the hip (pretreatment; anterior view) in a 17-year-old male secondary to a motor vehicle accident. The wound had been serially debrided because of progressive muscle necrosis and *Pseudomonas myocytitis*. (B) Posterior view of wound pretreatment. The wound was treated with subatmospheric pressure, with 2,000 ml of fluid removed per day for the first several days. Tissue turgor rapidly resolved and muscle bellies realigned. After 12 days of the treatment, meshed split-thickness skin grafts were placed and The V.A.C. was used for 4 additional days to secure grafts to the wound surface. (C) Split-thickness skin graft in place on posterior of wound. (D) Posterior wound site 2 months postgrafting.

effluent removed during subatmospheric pressure treatment.

Concomitant with the increases in vascularity and in the rate of granulation formation, there is a significant decrease in bacterial colonization, as evidenced by decreases in superficial purulence, slime formation, and odor. Histological and Gram's stains of the effluent show large numbers of bacteria and white cells. Bacterial counts of human wound tissues treated with the vacuum-assisted closure technique have demonstrated a significant quantitative decrease after 3 to 4 days, paralleling decreases observed in animal studies. While the wound remains colonized as long as it is not epithelialized, the number of bacteria is

usually less than  $10^2$  or  $10^3$  per gram of tissue. Successful wound healing correlates with bacterial counts of less than  $10^5$  organism per gram of tissue [13]. Increases in local circulation and tissue oxygen levels enhance the resistance of that tissue to infection and reduce the potential for anaerobic colonization, which is known to slow healing [14–16].

The initial treatment concept was based on simple mechanics and physics. During therapy, the application of subatmospheric pressure causes the reticulated foam dressing to collapse and the resultant forces are transmitted to all wound surfaces in contact with the foam dressing. Living tissues are known to respond to the



A



B

*Fig 9. (A) Abdominal wound with exposed mesh (pretreatment) of a 38-year-old patient following surgery to remove the spleen, partial colectomy, and resection of small bowel secondary to shotgun wound. Due to extensive soft-tissue loss, a Marlex mesh had been placed to restore abdominal wall integrity. The wound was treated with subatmospheric pressure for 5 weeks, at which time the wound was flush with surrounding tissue, had contracted to 40% its original size, and a healthy bed of granulation tissue was present. A meshed split-thickness skin graft was placed over the granulation tissue. (B) Wound 3 weeks postgrafting.*

application of controlled force. As early as 1911 it was postulated that application of mechanical stress would result in angiogenesis and tissue growth [17]. More recently, soft-tissue expansion and the Ilizarov bone distraction procedures both employ the application of a controlled distraction force on living cells and tissues [18-23]. In response to the applied forces, an increased rate of mitosis is induced, new vessels are formed, and adjacent tissues are recruited through viscoelastic flow [24-27].

Sutures and more recently introduced mechanical devices induce a limited traction force that is concentrated on a small number of points in the adjacent tissues, mobilizing them into the defect. In cases with substantial tissue loss, or when large forces are required to oppose the wound edges, either the caliber or number of sutures must increase to avoid failure of the suture material or disruption of tissues. However, as both the diameter and number of sutures increase, so does the potential for infection [28, 29]. Unlike sutures or other mechanical tension devices, The V.A.C. technique applies its mechanical advantage uniformly to every point on the inner surface of the wound in a controlled manner. The force exerted on an individual point at the edge of the wound toward the geometric center of the defect is small, but the sum of the forces applied becomes very large.

It must be emphasized that the vacuum-assisted closure technique was developed as an adjunct to wound care. It is not meant to, and will never, replace surgical procedures. In most cases, the technique presented is used to prepare the wound bed so that a lesser surgical procedure can be performed with a greater chance for successful wound closure, minimizing time to complete wound closure and thus minimizing cost and hospitalization. However, there are patients unable to undergo surgical procedures who can be efficaciously treated to complete closure with diminution of pain and suffering at minimal expense and hospitalization. Studies at our institution revealed that the cost of treatment of chronic wounds assigned to Diagnosis-Related Group 263 (skin graft and/or debridement for skin ulcer or cellulitis with chief complaint) has been decreased by 65% since initiation of The V.A.C. device [30]. The ultimate aim of all treatment should be to achieve a closed wound in the shortest possible period of time with the least trauma to the patient.

Despite the relatively large number of patients treated ( $N = 300$ ), the method of treatment described in this paper is early in the course of its development and application. All areas in this method of treatment need further investigation. We have recognized 34 independent variables that influence wound healing in our patients. A randomized, prospective, comparative study



would thus require very large numbers of wounds and is presently underway. The authors feel that the dissemination of this information to the medical community at this time, even before randomized studies are completed, will prompt further studies by other individuals and institutions to corroborate and further develop this technique. It is the experience of the authors that this technique can be applied to a wide variety of defects, improving the quality of life of our patients.

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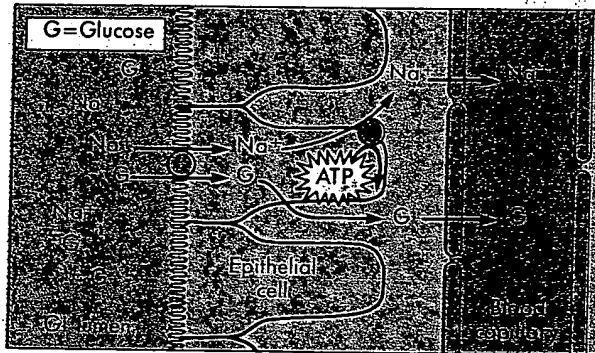
**absorbent** /absôr'bənt/ [L, *absorbere*, to suck up], 1. capable of attracting and absorbing substances into itself. 2. a product or substance that can absorb liquids or gases.

**absorbent dressing**, a dressing of any material applied to a wound or incision to absorb secretions.

**absorbent gauze**, a gauze for absorbing fluids. The form, weight, and use vary. Gauze may be a fine fabric in rolled single layers for spiral bandages, or it may be a thick, many-layered pad for a sterile pressure dressing.

**absorbifacient** /absôr'bifa'shənt/ [L, *absorbere* + *facere*, to make], 1. any agent that promotes or enhances absorption. 2. causing or enhancing absorption.

**absorption** /absôr'p'shən/ [L, *absorbere*], 1. the incorporation of matter by other matter through chemical, molecular, or physical action, such as the dissolving of a gas in a liquid or the taking up of a liquid by a porous solid. 2. (in physiology) the passage of substances across and into tissues, such as the passage of digested food molecules into intestinal cells or the passage of liquids into kidney tubules. Kinds of absorption are **agglutinin absorption**, **cutaneous absorption**, **external absorption**, **intestinal absorption**, **parenteral absorption**, and **pathologic absorption**. 3. (in radiology) the process of absorbing radiant energy by living or nonliving matter with which the radiation interacts.



**Absorption of sodium, glucose, and amino acids**  
(Thibodeau, 1993/Rolin Graphics)

**absorption coefficient**, (in radiology) the fractional loss in intensity of electromagnetic energy as it interacts with an absorbing material. It is usually expressed per unit of thickness or per unit mass.

**absorption rate constant**, a value describing how much drug is absorbed per unit of time.

**absorption spectrum**, the range of electromagnetic energy that is used for spectroanalysis, including both visible light and ultraviolet radiation; also, a graph of spectrum for a specific compound.

**absorptivity** /ab'sôrptiv'itē/, absorbance divided by the product of the concentration of a substance and the sample path length.

**abstinence** /ab'stinəns/, voluntary avoidance of a substance or the performance of an act for which the person has an appetite.

**abstinence syndrome** [L, *abstinere*, to hold back; Gk, *syn*, together, *dromos*, course], the withdrawal symptoms experienced by a chemically dependent person who is suddenly deprived of a regular intake of alcohol or other drugs.

**abstract** /ab'strakt, abstrakt'/, a condensed summary of a scientific article, literary piece, or address.

**abstraction** /abstrak'shən/ [L, *abstrahere*, to drag away], a condition in which the teeth or other maxillary and mandibular structures are below their normal position or away from the occlusal plane.

**abstract thinking**, the final stage in the development of the cognitive thought processes. During this phase, thought is characterized by adaptability, flexibility, and the use of concepts and generalizations. Problem solving is accomplished by drawing logical conclusions from a set of observations, such as making hypotheses and testing them. This type of thinking appears from about 12 to 15 years of age, usually after some degree of education. Compare **concrete thinking**, **syncretic thinking**.

**abulia** /əbūō'lyə/ [Gk, *a*, *boule*, not will], a loss of the ability or a reduced capacity to exhibit initiative or to make decisions. Also spelled **aboulia**.

**abuse** /əbyūs'/ [L, *abuti*, to waste], 1. improper use of equipment, a substance, or a service, such as a drug or program, either intentionally or unintentionally. See also **drug abuse**. 2. to physically or verbally attack or injure. A kind of abuse is **child abuse**.

**abuse of the elderly**, physical, psychologic, or material abuse, as well as violation of the rights of safety, security, and adequate health care of older adults. The victim of such abuse is generally an older woman with physical or mental impairment who lives with an adult child or another relative. Abusers are often middle-aged women, related or unrelated caretakers, who are themselves under stress. Contributing factors may include economics, interpersonal conflicts, health, and dependency. Often the abused person denies that abusive acts occur, leading to a climate of helplessness and resignation to abuse. The condition is often corrected by placing the abused adult in a protected setting away from the family, by vacations that provide respite for the family and older adult, and by sharing of caretaking responsibilities among children.

**abutment** /əbut'mənt/ [Fr, *abouter* to place end to end], a tooth, root, or implant which serves to support and retention of a fixed or movable prosthesis.

**abutment tooth**, a tooth selected to support a prosthesis.

**ABVD**, an anticancer drug combination of doxorubicin, bleomycin, vinblastine, and dacarbazine.

**Ac**, symbol for the element actinium.

**AC**, 1. abbreviation for **alternating current**. 2. abbreviation for **accommodative convergence**. See **AC/A ratio**.

**ac-**. See **ad-**.

**a.c.**, (in prescriptions) abbreviation for *ante cibum*, a Latin phrase meaning 'before meals.' The times of administration are commonly 7 AM, 11 AM, and 5 PM.

**A-C**, abbreviation for **alveolar-capillary**.

**acacia gum**, a dried, gummy exudate of the acacia tree (*Acacia senegal*) used as a suspending or emulsifying agent in medicines.

**academic ladder** /ak'ədem'ik/ [Gk, *akademeia*, school], the hierarchy of faculty appointments in a university through which a faculty member must advance from the rank of in-

anesthetics, corticosteroids, and antihistamines are used as antipruritic agents.

**antipsoriatic** /an'tisôr'ê-at'ik/ [Gk, *anti* + *psora*, itch], pertaining to an agent that relieves the symptoms of psoriasis.

**antipsychotic** /-sîkot'ik/ [Gk, *anti* + *psyche*, mind, *osis*, condition], 1. of or pertaining to a substance or procedure that counteracts or diminishes symptoms of a psychosis. 2. an antipsychotic drug. Phenothiazine derivatives are the most frequently prescribed antipsychotics for use in the treatment of schizophrenia and other major affective disorders. They apparently act by enhancing the filtering mechanisms of the reticular formation in the brainstem and by blocking central dopamine receptors. Common side effects of phenothiazines are a dry mouth, blurred vision, and extrapyramidal reactions requiring treatment with antiparkinsonian agents. See also **antidepressant**, **neuroleptic**, **tranquillizer**.

**antipyresis** /-pîrê'sis/ [Gk, *anti* + *pyretos*, fever], treatment to reduce and ameliorate fever.

**antipyretic** /-pîret'ik/ [Gk, *anti* + *pyretos*, fever], 1. of or pertaining to a substance or procedure that reduces fever. 2. an antipyretic agent. Such drugs usually lower the thermoregulation set point of the hypothalamic heat regulatory center, with resulting vasodilatation and sweating. Widely used antipyretic agents are acetaminophen, administered orally or through rectal suppositories, aspirin, and other salicylates. A tepid alcohol sponge bath or lukewarm tub bath may decrease an elevated temperature, and hypothermia produced by a cooling blanket is sometimes used for patients with a prolonged, high fever. Also called **antifebrile**, **antithermic**, **febrifuge**.

**antipyretic bath**, a bath in which tepid water is used to reduce the temperature of the body.

**antipyrotic** /-pîrot'ik/ [Gk, *anti* + *pyr*, fire], pertaining to the treatment of burns or scalds.

**antirickettsial** /-rêkit'ik/, pertaining to an agent used to treat rickettsias.

**antirheumatic** /-rôomat'ik/ [Gk, *anti* + *rheumatismos*, that which flows], pertaining to the relief of symptoms of any painful or immobilizing disorder of the musculoskeletal system.

**antiscorbutic vitamin**. See **ascorbic acid**.

**antiseborrheic** /-seb'ôrê'ik/, pertaining to a drug or agent that is applied to the skin to control seborrhea or seborrheic dermatitis. Antiseborrheic preparations usually contain salicylic acid, resorcinol, sulfur, selenium sulfide, pyrithione zinc, or benzalkonium chloride.

**antisense** /an'têsens/, (molecular genetics) an RNA molecule that is complementary to the mRNA (sense) molecule produced by transcription of a given gene. The antisense strands of many genes have been synthesized in the laboratory and are useful because they hybridize with the mRNA sense strand and block their translation into amino acids and proteins.

**antiseptis** /-sep'sis/ [Gk, *anti* + *sepein*, putrefaction], destruction of microorganisms to prevent infection.

**antiseptic** /-sep'tik/, 1. tending to inhibit the growth and reproduction of microorganisms. 2. a substance that tends to inhibit the growth and reproduction of microorganisms.

**antiseptic dressing**, a dressing treated with an antiseptic, germicide, or bacteriostat, applied to a wound or an incision to prevent or treat infection.

**antiseptic gauze**, gauze permeated with an antiseptic solution, sometimes packaged in individual, sealed packets.

**antiserum** /an'tisîr'əm/, *pl.* antisera, antisera [Gk, *anti* + *L*, whey], serum of an animal or human containing antibodies against a specific disease, used to confer passive immunity to that disease. Antisera do not provoke production of antibodies. There are two types of antiserum. Antitoxin is an antiserum that neutralizes the toxin produced by specific bacteria, but it does not kill the bacteria. An antimicrobial serum acts to destroy bacteria by making them more susceptible to the leukocytic action. Polyvalent antiserum acts on more than one strain of bacteria; univalent antiserum acts on only one strain. Antibiotic drugs have largely replaced antimicrobial antisera. Caution is always to be used in giving antiserum of any kind, as hepatitis or hypersensitivity reactions can occur. Also called **immune serum**. Compare **vaccine**.

**antiserum anaphylaxis**, an exaggerated reaction of hypersensitivity in a normal person caused by the injection of serum from a sensitized individual. Also called **passive anaphylaxis**.

**antisepsis**. See **antiseptic gauze**.

**antisialogogue** /-sî'al'ægôg/ [Gk, *anti* + *sialon*, saliva, *agogos*, leading], a drug that reduces saliva secretion.

**antisocial personality** /-sô'shal/ [Gk, *anti* + *L*, social companion], a person who exhibits attitudes and overt behavior contrary to the customs, standards, and moral principles accepted by society. Also called **psychopathic personality**, **sociopathic personality**. See also **antisocial personality disorder**.

**antisocial personality disorder**, a condition characterized by repetitive behavioral patterns that lack moral or ethical standards and bring a person into continuous conflict with society. Symptoms include aggressiveness, egotism, impulsiveness, irresponsibility, hostility, a low frustration level, a marked emotional immaturity, and poor judgment. A person who has this disorder neglects the rights of others, is incapable of loyalty to others or to social values, is unable to feel guilt or to learn from experience, impervious to punishment, and tends to rationalize his behavior or to blame it on others. Also called **antisocial personality**. See also **psychopathic**.

**antisocial reaction**. See **antisocial personality disorder**.  
**antispasmodic** /-spazmod'ik/, a drug or other agent that prevents smooth muscle spasms, as in the uterus, digestive system, or urinary tract. Belladonna and dicyclanil hydrochloride are among drugs used in antispasmodic preparations.

**antistreptolysin-O test (ASOT, ASLT)** /an'tistîr'etôlî'sînô'/. a streptococcal antibody test for finding and measuring serum antibodies to streptolysin-O, an exotoxin produced by most group A and some group C and G streptococci. The test is often used as an aid in the diagnosis of rheumatic fever and glomerulonephritis. A low titer of antistreptolysin-O antibody is present in most people, but in streptococcal infection is common. Elevated or increasing titers indicate a recent infection. The normal findings in adults are equal to or less than 160 Todd units/ml. See also **Lancefield's classification**.

**antithermic**. See **antipyretic**.

**antithymocyte globulin (ATG)** /an'tithî'mâsîv/, gamma globulin fraction rendered immune to T lymphocytes.

**antithyroid drug** /-thî'roid/, any one of several preparations that can inhibit the synthesis of thyroid hormones; are commonly used in the treatment of hyperthyroidism. The major antithyroid drugs are thioamides, such as propylthiouracil.

**-dralazine**, a suffix for the name of an antihypertensive.  
**dram (dr.)** [Gk, *drachme*, weight of the same value], a unit of mass equivalent to an apothecaries' measure of 60 grains or  $\frac{1}{8}$  ounce and to  $\frac{1}{16}$  ounce or 27.34 grains avoirdupois. Also spelled **drachm (dr.)**.

**Dramamine**, a trademark for an antihistamine (dimenhydrinate), used as an antiemetic.

**dramatic play** /dramat'ik/ [Gk, *drama*, deed; AS, *plegan*, game], an imitative activity in which a child fantasizes and acts out various domestic and social roles and situations, as rocking a doll, pretending to be a doctor or nurse, or teaching school. It is the predominant form of play among preschool children.

**drape** [ME, *drap*, cloth], a sheet of fabric or paper, usually the size of a small bed sheet, for covering all or a part of a person's body during a physical examination or treatment. —**drape**, *v.*

**Draw-a-Person Test (DAP)** [AS, *dragan*; L, *personalis*, *testum*, crucible], a test developed by Karen Machover [American psychologist, b. 1902] based on the interpretation of drawings of human figures of both sexes. Interpretation depends upon the subject's verbalizations, self-image, anxiety, and sexual conflicts and other factors. Also called **Machover Draw-a-Person Test**.

**drawer sign** [AS, *dragan*, to drag], a diagnostic sign of a ruptured or torn knee ligament. It is tested by having the patient flex the knee at a right angle while the examiner grasps the lower leg just below the knee and moves the leg first toward, then away from himself or herself. The test is positive for the knee injury if the head of the tibia can be moved more than a half inch from the joint.

**drawing**, *informal*: a vague sensation of muscle tension.

**drawsheet**, a sheet that is smaller than a bottom or top sheet of a bed and is usually placed over the middle of the bottom sheet to keep the mattress and bottom linens dry. The drawsheet can also be used to turn or move a patient in bed.

**dream** [ME, *dreem*, joyful noise], 1. a sequence of ideas, thoughts, emotions, or images that pass through the mind during the rapid-eye-movement stage of sleep. 2. the sleeping state in which this process occurs. 3. a visionary creation of the imagination experienced during wakefulness. 4. (in psychoanalysis) the expression of thoughts, emotions, memories, or impulses repressed from the consciousness. 5. (in analytic psychology) the wishes, emotions, and impulses that reflect the personal unconscious and the archetypes that originate in the collective unconscious. See also **dream analysis**, **dream state**.

**dream analysis**, a process of gaining access to the unconscious mind by means of examining the content of dreams, usually through the method of free association.

**dream association**, a relationship of thoughts or emotions discovered or experienced when a dream is remembered or analyzed. See also **dream analysis**.

**dream state**, a condition of altered consciousness in which a person does not recognize the environment and reacts in a manner opposed to his or her usual behavior, as by flight or an act of violence. The state is seen in epilepsy and certain neuroses. See also **automatism**, **fugue**.

**drepanocytic anemia** /drep'anōsit'ik/ [Gk, *drepane*, sickle, *kytos*, cell], sickle cell anemia.

**dress code** [OFr, *dresser*, to arrange; L, *codex*, book], the standards set by an institution for the dress of the members of the institution.



**Drawer sign** (Seidel, 1991)

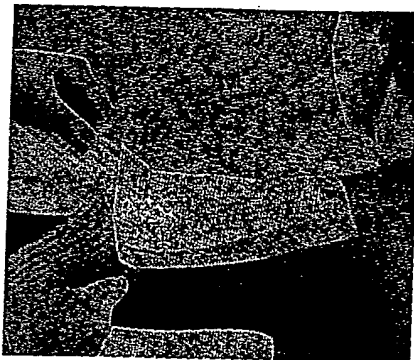
**dress** [OFr, *dresser*, to arrange], a clean or sterile covering applied directly to wounded or diseased tissue for absorption of secretions, for protection from trauma, for administration of medications, to keep the wound clean, or to stop bleeding. Kinds of dressings include **absorbent dressing**, **antiseptic dressing**, **occlusive dressing**, **pressure dressing**, and **wet dressing**.

**dresser forceps**, a kind of forceps that has narrow blade and blunt or notched teeth, designed for dressing wounds removing drainage tubes, or extracting fragments of necrotic tissue.

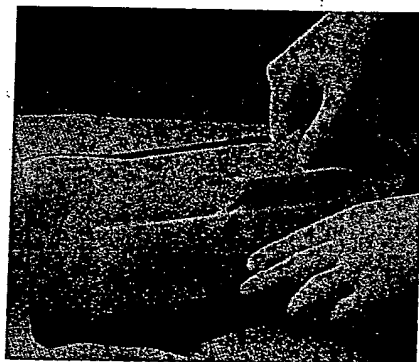
**Dressler's syndrome** /dres'lərz/, an autoimmune disorder that may occur several days after acute coronary infarction characterized by fever, pericarditis, pleurisy, pleural effusions, and joint pain. It results from the body's immunologic response to a damaged myocardium and pericardium.



Mepore



Airstrip



Simple dressings (Morison, 1992)

Treatment usually includes intensive aspirin therapy and, in severe cases, corticosteroids. A similar syndrome may occur after cardiac surgery.

**DRG**, abbreviation for **diagnosis related groups**.

**drift** [AS, *drifan*, to move forward], 1. **antigenic drift**, a change that occurs in a strain of virus so that variations appear periodically with alterations in antigenic qualities. 2. **genetic drift**, random variations in gene frequency of a population from one generation to the next.

**drifting tooth**, any one of the teeth that migrate from normal position in the associated dental arch. This anomaly may result from the loss of proximal support, loss of functional antagonists, occlusal traumatic tooth relationships, inflammatory and retrograde changes in the attachment apparatus, or oral habits, such as thumb-sucking and bruxism.

**Drinker respirator** [Philip Drinker, American engineer, b. 1893], an airtight respirator consisting of a metal tank that encloses the entire body, except for the head. Used for long-term therapy, it alternates positive and negative air pressure within the tank, providing artificial respiration by contracting and expanding the walls of the chest. Also called **artificial lung**, **iron lung**.

**drip** [AS, *dryppan*, to fall in drops], 1. the process of a liquid or moisture forming and falling in drops. Kinds of drip are **nasal drip** and **postnasal drip**. 2. the slow but continuous infusion of a liquid into the body, as into the stomach or a vein. 3. to infuse a liquid continuously into the body.

**drip gavage**, a method of feeding a liquid formula diet

through a tube inserted through the nostrils to the stomach. The formula may be heated to about 100° F or administered at room temperature and is contained in a bag suspended from a stand. It may also be administered with the use of a feeding pump.

**drip system**, (in intravenous therapy) an apparatus for delivering specific volumes of intravenous solutions within predetermined periods of time and at a specific flow rate. See also **macro drip**, **micro drip**.

**drive** [AS, *drifan*, to move forward], 1. a basic, compelling urge. **Primary drive** refers to one that is innate and in close contact with physiologic processes. A **secondary drive** is one that evolves during the process of growth and that incites and directs behavior. 2. an electromechanic device that holds a secondary-storage medium and allows for the transfer of data to and from the computer, such as a disk drive or tape drive.

**Drixoral**, a trademark for a fixed-combination drug containing an antihistamine (dextbrompheniramine maleate) and a vasoconstrictor and bronchodilator (pseudoephedrine sulfate), used for the relief of congestion of the upper respiratory tract.

**-drome**, a suffix meaning 'that which runs or moves together' in a specified way: *dermadrome*, *heterodrome*, *syn-drome*.

**dromo-**, a combining form meaning 'pertaining to running or conduction': *dromomania*, *dromophobic*, *dromotropic*.

**dromostanolone propionate** /drō'mostan'əlōn/, a synthetic androgen.

■ **INDICATION**: It is prescribed for female breast cancer.

■ **CONTRAINDICATIONS**: It is not used for male breast cancer or in premenopausal women.

■ **ADVERSE EFFECTS**: Among the more serious adverse reactions are masculinization, edema, and hypercalcemia.

**dronabinol** /drōnab'inol/, an oral antiemetic.

■ **INDICATIONS**: It is prescribed for refractory nausea and vomiting caused by cancer chemotherapy.

■ **CONTRAINDICATIONS**: Dronabinol should not be given to persons who are hypersensitive to the product or to THC, the active ingredient of the drug.

■ **ADVERSE EFFECTS**: Dronabinol is a Schedule II controlled substance with a high potential for abuse. It can produce both physical and psychologic dependence. It is not recommended for patients taking a central nervous system depressant or other psychoactive drugs. Among adverse effects reported are drowsiness, dizziness, impaired coordination, and hallucinations.

**drop** [AS *dropa*], a small spherical mass of liquid. A drop may vary in size with differences in temperature, viscosity, and other factors. For therapeutic purposes, a drop is regarded as having a volume of .06 to 0.1 ml, or 1 to 1.5 minims.

**drop arm test**, a diagnostic test for a tear in the supraspinatus tendon. It is positive if the patient is unable to slowly and smoothly lower the affected arm from a position of 90 degrees of abduction.

**drop attack**, a form of transient ischemic attack (TIA) in which a brief interruption of cerebral blood flow results in a person falling to the floor without losing consciousness. The episode may affect the person's sense of balance or leg muscle tone, causing the collapse. A contributing factor may also be a weakness of the leg muscles or a hip or knee joint dysfunction.

**droperidol** /drōper'ədol/, an antipsychotic, sedative drug

2. situated near the occipital bone, such as the occipital lobe of the brain.

**occipital artery**, one of a pair of tortuous branches from the external carotid arteries that divides into six branches and supplies parts of the head and scalp. Each terminal portion at the vertex of the skull is accompanied by the greater occipital nerve.

**occipital bone**, the cuplike bone at the back of the skull, marked by a large opening, the foramen magnum, that communicates with the vertebral canal. Its inner surface is divided into four fossae. The occipital bone articulates with the two parietal bones, the two temporal bones, the sphenoid, and the atlas.

**occipital lobe**, one of the five lobes of each cerebral hemisphere, occupying a relatively small pyramidal portion of the occipital pole. The occipital lobe lies beneath the occipital bone and presents medial, lateral, and inferior surfaces. The medial surface is bounded anteriorly by the parietooccipital sulcus and the preoccipital notch and is divided by the posterior calcarine sulcus into the wedge-shaped cuneus and the lingual gyrus. The lateral surface of the lobe is divided by the lateral sulcus into the superior and the inferior occipital gyri. An imaginary transverse line across the preoccipital notch limits the inferior surface. Compare **central lobe**, **frontal lobe**, **parietal lobe**, **temporal lobe**.

**occipital sinus**, the smallest of the cranial sinuses and one of six posterior superior venous channels associated with the dura mater. It is located in the attached margin of the falx cerebelli, courses around the foramen magnum by several small channels, communicates with the posterior internal vertebral venous plexuses, and ends in the confluence of the sinuses. Compare **inferior sagittal sinus**, **straight sinus**, **superior sagittal sinus**.

**occipito-**. See **occipit-**.

**occipitoaxial ligament**. See **membrana tectoria**.

**occipitobregmatic** /oksip'itöbregmat'ik/ [L, *occiput* + Gk, *bregmā*, front of the head], of or pertaining to the occiput and the bregma.

**occipitofrontal** /oksip'itöfrun'təl/ [L, *occiput* + *frons*, forehead], of or pertaining to the occiput and the frontal bone of the skull.

**occipitofrontalis** /oksip'itöfrantal'is/, one of a pair of thin, broad muscles covering the top of the skull, consisting of an occipital belly and a frontal belly connected by an extensive aponeurosis. The frontal belly originates at the galea aponeurotica and inserts in the skin of the eyebrows and the nose. The occipital belly originates in the superior nuchal line of the occipital bone and inserts at the galea aponeurotica. The occipitofrontalis is innervated by the facial nerve. It is the muscle that draws the scalp and raises the eyebrows. Compare **temporoparietalis**.

**occipitoparietal fissure**. See **parietooccipital sulcus**.

**occiput** /ok'sipət/, pl. **occiputs**, **occipita** /oksip'itə/, the back part of the head. Also called **occiput cranii**.

**occluded** /əklōō'did/ [L, *occludere*, to shut up], closed, plugged, or obstructed.

**occlusal** /əklōō'səl/ [L, *occludere*, to close up], pertaining to a closure, such as the contact between the teeth of the upper and lower jaws.

**occlusal adjustment**, (in dentistry) the grinding of the occluding surfaces of teeth to improve the occlusion or relationship between opposing tooth surfaces, their supporting

structures, the muscles of mastication, and the temporomandibular joints.

**occlusal contouring**, the modification by grinding of irregularities of occlusal tooth forms, such as uneven marginal ridges, and extruded or malpositioned teeth.

**occlusal form**, the shape of the occluding surfaces of a tooth, a row of teeth, or any dentition.

**occlusal harmony**, a combination of healthy and nondisruptive occlusal relationships between the teeth and their supporting structures, the associated neuromuscular mechanisms, and the temporomandibular joints.

**occlusal lug**. See **occlusal rest**.

**occlusal plane** [L, *occludere*, to close up + *planum*, level ground], a plane passing through the occlusal surfaces of the teeth. It represents the mean of the curvature of the occlusal or biting surface.

**occlusal radiograph**, an intraoral radiograph made with the film placed on the occlusal surfaces of one of the arches. It shows the relationship of teeth to the underlying structures in the alveolar process, such as cysts and abscesses.

**occlusal recontouring**, the reshaping of an occlusal surface of a natural or artificial tooth.

**occlusal relationship**, the relationship of the mandibular teeth to the maxillary teeth when in a defined occlusal contact position.

**occlusal rest**, a support which is part of a removable partial denture and which is placed on the occlusal surface of a posterior tooth. Also called **occlusal lug**.

**occlusal rest angle**, (in dentistry) the angle formed by the occlusal rest with the upright minor connector. Also called **rest angle**.

**occlusal spillway**, a natural groove that crosses a cusp ridge or a marginal ridge of a tooth.

**occlusal surface** [L, *occludere*, to close up; *superficies*, surface], the surfaces of teeth in one arch that makes contact or near contact with the corresponding surfaces of the teeth in the opposing arch. Also called **masticatory surface**.

**occlusal trauma**, injury to a tooth and surrounding structures caused by malocclusive stresses, including trauma, temporomandibular joint dysfunction, and bruxism.

**occlusion** /əklōō'zhən/ [L, *occludere*, to shut up], 1. (in anatomy) a blockage in a canal, vessel, or passage of the body. 2. (in dentistry) any contact between the incising or masticating surfaces of the maxillary and mandibular teeth. -**occlude**, v., **occlusive**, *adj.*

**occlusion rim**, an artificial dental structure with occluding surfaces attached to temporary or permanent denture bases, used for recording the relation of the maxilla to the mandible and for positioning the teeth. Also called **bite block**.

**occlusive** /əklōō'siv/, pertaining to something that effects an occlusion or closure, such as an occlusive dressing.

**occlusive dressing**, a dressing that prevents air from reaching a wound or lesion and that retains moisture, heat, body fluids, and medication. It may consist of a sheet of thin plastic affixed with transparent tape.

**occlusometer**. See **gnathodynamometer**.

**occult** /əkul't/ [L, *occultare*, to hide], hidden or difficult to observe directly, such as occult prolapse of the umbilical cord or occult blood.

**occult blood**, blood that is not apparent grossly appears from a nonspecific source, with obscure signs and symptoms. It may be detected by means of a chemical test or by



**pressure bandage**, a bandage applied to stop bleeding, prevent edema, or provide support for varicose veins.

**pressure dressing**, a dressing firmly applied to exert pressure, usually on a wound for hemostasis.

**pressure edema**, 1. edema of the lower extremities caused by pressure of a pregnant uterus against the large veins of the area. 2. edema of the fetal scalp after cephalic presentation.

**pressure necrosis**. See *decubitus ulcer*.

**pressure point**, 1. a point over an artery where the pulse may be felt. Pressure on the point may be helpful in stopping the flow of blood from a wound distal to the point. 2. a site that is extremely sensitive to pressure, such as the phrenic pressure point along the phrenic nerve between the sternocleidomastoid and the scalenus anticus on the right side; pressure at this site may be symptomatic of gallbladder dysfunction.

**pressure-sensitive adhesive**, a drug-delivery device that uses polymers that are permanently tacky at room temperature and will adhere to the skin when slight pressure is applied.

**pressure sore**. See *decubitus ulcer*.

**pressure support ventilation (PSV)**, the augmentation for spontaneous breathing effort with a specific amount of positive airway pressure. The patient initiates the inspiratory flow, generating his or her own  $V_t$  and frequencies.

**pressure ventilator**, a ventilator in which gas delivery is limited by a predetermined pressure.

**pressure ulcer**. See *decubitus ulcer*.

**presumptive signs** /-sump'tiv/ [L, *praesumere*, to take beforehand; *signum*, mark], manifestations that indicate a pregnancy although they are not necessarily positive. Presumptive signs may include cessation of menses and morning sickness. See also *Chadwick's sign*.

**preswing stance stage** /prē'swing/ [L, *prae* + AS, *swingan*, to fling; L, *stare*, to stand; OFr, *estage*, stage], one of the five stages in the stance phase of walking or gait, involving a brief transitional period of double limb support during which one leg of the body is rapidly relieved of body-bearing weight and prepared for the swing forward. The type of preswing used by an individual is a factor in the diagnoses of many abnormal orthopedic conditions. Compare *initial contact stance stage*, *loading response stance stage*, *midstance*, *terminal stance*. See also *swing phase of gait*.

**presymptomatic disease** /-simp'tamat'ik/ [L, *prae* + Gk, *symptoma*, a happening], an early stage of disease when physiologic changes have begun although no signs or symptoms are observed.

**presynaptic** /-sinap'tik/ [L, *prae* + *synaptein*, to join], 1. situated near or before a synapse. 2. before a synapse is crossed.

**presystolic** /-sis'talē/ [L, *pre*, before; Gk, *systole*, contraction], an interval in the cardiac cycle immediately before systole.

**presystolic** /-sistol'ik/ [L, *prae* + Gk, *systole*, contraction], of or pertaining to the period preceding systole.

**presystolic murmur** [L, *pre*, before; Gk, *systole*; L, *murmur*, humming], a heart murmur in cases of mitral stenosis, before diastole.

**preterm** /prē'turm/ [L, *pre*, before; Gk, *terma*, limit], 1. events before a specific date. 2. pertaining to a shorter than normal period of gestation.

**preterm birth**, any birth that occurs before the thirty-seventh week of gestation. See also *premature infant*.

**preterm infant**. See *premature infant*.

**preterm labor**. See *premature labor*.

**pretibial** /prētib'ē-əl/ [L, *prae* + *tibia*, shinbone], of or pertaining to the area of the leg in front of the tibia.

**pretibial fever**, an acute infection caused by *Leptospira autumnalis*, characterized by headache, chills, fever, enlarged spleen, myalgia, low white blood cell count, and a rash on the anterior surface of the legs. Also called *Fort Bragg fever*.

**pretrial discovery**. See *discovery*.

**prevalence** /prev'eləns/ [L, *praevalentia*, a powerful force], (in epidemiology) the number of all new and old cases of a disease or occurrences of an event during a particular period of time. Prevalence is expressed as a ratio in which the number of events is the numerator and the population at risk is the denominator. See also *rate*.

**prevention** /-ven'shən/ [L, *praevenire*, to anticipate], (in nursing care) any action directed toward preventing illness and promoting health to avoid the need for secondary or tertiary health care. Prevention includes such nursing actions as assessment; application of prescribed measures, such as immunization; health teaching; early diagnosis and treatment; and recognition of disability limitations and rehabilitation potential. In acute care nursing, many interventions are simultaneously therapeutic and preventive.

**preventive** /-ven'tiv/ [L, *praevenire*, to anticipate], tending to slow, stop, or interrupt the course of an illness or to decrease the incidence of a disease.

**preventive care**, a pattern of nursing and medical care that focuses on the prevention of disease and health maintenance and includes early diagnosis of disease, discovery and identification of people at risk of developing specific problems, counseling, and other intervention to avert a health problem. Screening tests, health education, and immunization programs are common examples of preventive care. Also called *primary nursing*.

**preventive dentistry** [L, *praevenire*, to anticipate + *dens*, tooth], the science of the prevention of disease affecting the teeth.

**preventive health care**. See *preventive care*.

**preventive medicine** [L, *praevenire*, to anticipate + *medicina*], the branch of medicine that is concerned with the prevention of disease and methods for increasing the power of the patient and community to resist disease and prolong life.

**preventive nursing** [L, *praevenire*, to anticipate + *nutrix*, nurse], the branch of nursing that is concerned with general health promotion, teaching of early recognition and treatment of disease, encouraging lifestyle modification, and prevention of further deterioration of the disabled.

**preventive psychiatry**, the use of theoretical knowledge and skills to plan and implement programs designed to achieve primary, secondary, and tertiary prevention.

**preventive treatment**, a procedure, measure, substance, or program designed to prevent a disease from occurring or a mild disorder from becoming more severe. Various diseases are prevented by immunizations with vaccines, anti-septic measures, the avoidance of smoking, regular exercise, a prudent diet, adequate rest, the correction of congenital anomalies, and screening programs for the detection of preclinical signs of disorders. Also called *prophylactic treatment*.

**previa**. See *placenta previa*.

**previllous embryo** /prēvil'əs/ [L, *prae* + *villus*, hairy; Gk, *en in*, *bryein*, to grow], an embryo of a placental mam-

s is mass. See also mass ed bar that holds weights

less a state of absence he effects of gravity space medicine

n, the relationship of s grams of solute per ml example is 50 g of glucose W/V solution, even though

em of establishing units ces, including standards of

, trahere, to draw], tra a limb by means of a suture

osis.

[August F. L. Weismann ismus, practice], the basis of development as proposed by G. N. These state that the vegetative system, which is distinct from the somatoplasm, is inherited from one generation to the next. Development of the hereditary somatoplasm to give rise to changes in somatoplasm that acquired characteristics. Weismann's theory, germ theory, -weismannian

sign.

to wish; ME, *babe*; L, *salus*, health supervision for infants. Such health care measures to prevent disease and treatment of disease. Action in proper manner. Specific care and rearing of children. The schedule for children's health for the first 6 months of age, every 3 months every 6 months during the first year. Well baby care may be given at a local meeting place, or at a community health center or nurse practitioner's office.

hat specializes in medical care of infants.

on, to be], achievement as defined by the individual. **cytic malignant lymphoma**, a phagocytic malignant lymphoma characterized by the presence of lymphocytes. Also called **lymphocytic lymphoma**.

ents with unstable angina. The left anterior descending artery is normal or minimally dilated. ST segment elevation, no

of precordial R waves, progressive, deep, symmetrical inversion of the T waves in leads V2 and V3, but not confined to these leads. The ECG signs are seen when the patient is without pain.

**wellness**, a dynamic state of health in which an individual progresses toward a higher level of functioning, achieving an optimum balance between internal and external environments.

**welt** [OE, *wealtan*, to roll], a raised ridge on the skin, usually caused by a blow.

**wen**. See **pilar cyst**.

**Wenckebach heart block**. See **Mobitz I heart block**.

**Wenckebach periodicity** /veng'kəbāk, -bāk/ [Karel F. Wenckebach, Dutch-Austrian physician, b. 1864; Gk, *peri*, around, *hodos*, way], a form of second-degree atrioventricular block with a progressive beat-to-beat prolongation of the PR interval, finally resulting in a nonconducting P wave. At this point, the sequence recurs. Also called **Mobitz I**, **Type I block**, **Wenckebach phenomenon**. See also **atrioventricular block**.

**Werdnig-Hoffmann disease** /verd'nighōf'mun/ [Guido Werdnig, Austrian neurologist, b. 1862; Johann Hoffman, German neurologist, b. 1857], a genetic disorder beginning in infancy or young childhood, characterized by progressive atrophy of the skeletal muscle resulting from degeneration of the cells in the anterior horn of the spinal cord and the motor nuclei in the brainstem. Onset occurs within the first year of life, with the condition usually apparent at birth. Symptoms include congenital hypotonia, absence of stretch reflexes, flaccid paralysis, especially of the trunk and limbs, lack of sucking ability, fasciculations of the tongue and sometimes of other muscles, and, often, dysphagia. Treatment is symptomatic, and death generally occurs in early childhood, often from respiratory complications. The condition is transmitted as an autosomal recessive trait and occurs more frequently in siblings than in successive generations. Also called **familial spinal muscular atrophy**, **Hoffmann's atrophy**, **infantile spinal muscular atrophy**, **progressive spinal muscular atrophy of infants**, **Werdnig-Hoffmann paralysis**. See also **floppy infant syndrome**.

**Werthof's disease**. See **thrombocytopenic purpura**.

**Wernicke's center** [Karl Wernicke; Gk, *kentron*, center], a sensory speech center located in the posterior temporal gyrus and adjacent angular gyrus in the dominant hemisphere. Wernicke observed in 1874 that patients with brain damage in that area also suffered a loss of speech comprehension. Also called **Wernicke's area**, **Wernicke's field**, **Wernicke's zone**.

**Wernicke's encephalopathy** /ver'nikēz/ [Karl Wernicke, Polish neurologist, b. 1848], an inflammatory, hemorrhagic, degenerative condition of the brain, characterized by lesions in several parts of the brain, including the hypothalamus, mammillary bodies, and tissues surrounding ventricles and aqueducts. The condition is characterized by double vision, involuntary and rapid movements of the eyes, lack of muscular coordination, and decreased mental function, which may be mild or severe. Wernicke's encephalopathy is caused by a thiamine deficiency and is seen in association with chronic alcoholism. It also occurs as a complication of GI tract disease and hyperemesis gravidarum associated with malabsorption and malnutrition. Also called **Wernicke's syndrome**.

**Wernicke's field**, **Wernicke's zone**. See **Wernicke's center**.

**West African sleeping sickness**. See **Gambian trypanosomiasis**.

**Westcott**, a trademark for a glucocorticoid (hydrocortisone valerate).

**Westermarck's sign**, the absence of blood vessel markings beyond the location of a pulmonary embolism as seen on a radiograph.

**Western blot test**, a laboratory blood test to detect the presence of antibodies to specific antigens. It is regarded as more precise than the enzyme-linked immunosorbent assay (ELISA) and is sometimes used to check the validity of ELISA tests.

**western equine encephalitis**. See **equine encephalitis**.

**West nomogram**, a nomogram used in estimating the body surface area. See also **nomogram**.

**wet-and-dry-bulb thermometer**, an instrument used to measure the relative humidity of the atmosphere. It consists of a thermometer with a bulb that is wet or moist and one that is kept dry. The relative humidity is calculated from the difference in readings of the thermometers when water evaporates from the dry bulb, decreasing its temperature.

**wet cough**. See **productive cough**.

**wet dream**. See **nocturnal emission**.

**wet dressing** [AS, *waet*; OFr, *dresser*, to arrange], a moist dressing used to relieve symptoms of some skin diseases. As the moisture evaporates, it cools and dries the skin, softens dried blood and sera, and stimulates drainage. Medication may be added if necessary.

**wet lung**, an abnormal condition of the lungs, characterized by a persistent cough and crackles at the lung bases. It occurs in workers exposed to pulmonary irritants, such as ammonia, chlorine, sulfur dioxide, volatile organic acids, dusts, and vapors of corrosive chemicals. Treatment consists of removing the person from exposure to the irritant and therapy for possible pulmonary edema. Compare **pulmonary edema**. See also **ARDS**, **pleural effusion**, **pleurisy**.

**wet nurse**, a woman who cares for and breast-feeds another's infant.

**wet pack** [AS, *waet*, moist; ME, *pakke*], a therapy that involves wrapping the patient in wet sheets with a top covering of a dry blanket, usually to reduce fever.

**wet pleurisy** [AS, *waet*; Gk, *pleuritis*], pleurisy in which the inflammation has progressed to an effusive state, with the fluid having a high specific gravity because of the presence of blood clots and fibrin.

**wetting agent**, a detergent, such as tyloxapol, used as a mucolytic in respiratory therapy.

**W/F**, symbol for *white female*, often used in the initial identifying statement in a patient record.

**Wharton's jelly** /wōr'tən/ [Thomas Wharton, English anatomist, b. 1614; L, *gelare*, to congeal], a gelatinous tissue that remains when the embryonic body stalk blends with the yolk sac within the umbilical cord.

**wheal** /wēl/ [AS, *walu*, pimple], an individual lesion of urticaria.

**wheal-and-flare reaction** [AS, *walu*; *flare*; ME, *fleare*, to blaze up; L, *re*, *agere*, to act], a skin eruption that may follow injury or injection of an antigen. It is characterized by swelling and redness caused by a release of histamine. The reaction usually occurs in three stages, beginning with



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## DRAW 8

9) : poker in which each player is dealt  
betting may get replacements for discarded  
shāw\ n (1828) : DRAWKNIFF  
: a shot in billiards or pool made by hitting  
moves back after striking the object ball  
strin\ n (1845) : a string, cord, or tape  
through eyelets for use in closing  
ants or curtains  
(ca. 1891) : a telescoping tube  
ope)  
: to bring (as troops) into array 2  
(draw up plans) 3 : to bring to a halt  
to an erect posture esp. as an assertion of  
to come to a halt  
dray, a wheelless vehicle; akin to OE  
more at DRAW (14c) : a vehicle  
g cart or wagon without sides  
haul on a dray : CART  
(1791) : the work or cost of hauling by  
): a horse adapted for drawing heavy loads  
n (1581) : one whose work is hauling by  
ME dreden, fr. OE drædan v (bef. 12c)  
aic : to regard with awe 2 : to feel extreme  
e ~ vi : to be apprehensive or fearful  
a : great fear esp. in the face of impending  
ss in the face of a disagreeable prospect  
urhaic : AWE 2 : one causing fear or awe

causing great fear or anxiety 2 : inspiring  
adj (13c) 1 a : inspiring dread : causing  
b : inspiring awe or reverence 2 : extremely  
ant, or shocking 3 : EXTREME (~) dis-  
leat adv —dread-ful-ness\ -fal-ness\ n  
a cheap and sensational story or periodical  
lak\ n (1960) 1 : a narrow ropelike strand  
or braiding 2 pl : a hairstyle consisting of

sd-not, -nāt\ n (1806) 1 : a warm wrap  
the cloth 2 [Dreadnought, Brit. battleship  
it is among the largest and most powerful of  
often attrib [ME dream, fr. OE drem, noise-  
akin to OHG troum dream] (13c) 1 : a  
emotions occurring during sleep ~ com-  
ience of waking life having the characteris-  
sionary creation of the imagination : DREAM  
marked by abstraction or release from reality  
seen in a dreamlike state : VISION 3 :  
ty; excellence, or enjoyable quality (the new  
a : a strongly desired goal or purpose  
b : something that fully satisfies a wish  
met's ~) —dream-ful\ -fal\ adj —dream-  
ful-ness\ n —dream-ful-ness\ n —dream-  
less-ness\ n —dream-like\ -li\ adj —  
dream\ (pl, 'dremd\ or 'dremat\ -  
in\ v (13c) 1 : to have a dream 2 : to  
ing of a better future) 3 : to appear  
eafy shadows —Gladys Taber  
consider as a possibility : IMAGINE  
on (~ing the hours away) —  
a wouldn't dream of disturbing  
1 : one that dreams 2 : a  
fancy and imagination b : one who has  
garded as impractical : VISIONARY  
Jand\ n (ca. 1834) : an unreal delusion  
ination or in dreams : NEVER-NEVER LAND  
n, often cap (1896) : the time of creation  
stralian aborigines  
to form in the mind : DEVISE, CONCOCT  
6) : a usu. medieval poem having a frame-  
res himself as falling asleep and envisioning  
gorical people and events  
world\ n (1817) : a world of illusion or  
i dream-er, -est (1567) 1 a : full of  
b : pleasantly abstracted from immedi-  
g or fantasy (a ~ child) 3 a : sugges-  
sionary quality b : quiet and soothing  
s, so handsome... real ~ —Greg  
9) : dream-iness\ -me-ness\ n  
9) : DREAMY —dream\ n  
drea-ri-er, -est [ME dreyr, fr. OE drem  
akin to OHG truren to be sad, Goth  
eeling, displaying, or reflecting listless-  
ving nothing likely to provide cheer, com-  
ISMAL —drea-ri-ly\ -drir-ā-le\ adv

ek\ n [Yiddish drek & G Dreck, fr. ME  
bish] (1922) : TRASH, RUBBISH  
bredged; dredg-ing\ v (1508) 1 :  
th or as if with a dredge — often used  
erway) with a dredging machine 2 :  
ig — often used with up (dredging up  
dge 2 : to search deeply — dredg-er\ n  
assumed) OE dredge; akin to OE dregan  
l) 1 : an apparatus usu. in the form of a  
attached bag net used esp. for gathering  
ne for removing earth usu. by buckets or  
tube 3 : a barge used in dredging  
dredg-ing\ (obs. dredge, n. sweetmeat  
fragile, modif. of L tragema sweetmeat  
ema sweetmeat, fr. tragēin to gnaw)  
ng (as with flour) — dredg-er\ n

dree\ (dree\ v dred; dred-ing\ [ME, fr. OE drōgan; akin to Goth  
dree (to perform military service) (bef. 12c) chiefly Scot : ENDURE.

dreg\ (dreg\ v [ME, fr. ON dregg; perh. akin to L fraces dregs of oil]  
sediment contained in a liquid or precipitated from it : LEES  
in pl. 2 : the most undesirable part — usu. used in pl. 3  
the remaining part : VESTIGE — dredg-y\ -dre-gē\ adj

dregeon\ n (1930) : the lowest part of the ionosphere occurring ap-  
proximately between 30 and 55 miles (50 and 90 kilometers) above the  
surface of the earth

dreid\ (dreid\ v [ME, of Scand origin; akin to ON drjúgr lasting]  
dreid\ n (1930) : DREARY

dreidel\ (dreid\ n [Yiddish dreidl, fr.  
dreiden to turn; fr. MHG dregen, fr. OHG drāen —  
throw] (126) 1 : a 4-sided toy marked  
with Hebrew letters and spun like a top in a game of  
children's game of chance played esp. at  
Hanukkah with a dreidel

drech\ (drech\ n (bef. 12c) 1 : a poisonous or  
drinking; specif : a large dose of medicine  
mixed with liquid and put down the throat of an ani-  
mal 2 : something that drenches b : a quantity  
sufficient to drench or saturate

drech\ (ME, fr. OE drenchan; akin to OE drincan to  
drink) (12c) 1 : a archaic : to force to drink b  
to administer a drench to (an animal) 2 : to wet  
thoroughly (as by soaking or immersing in liquid) 3 : to soak or cover  
thoroughly as if by soaking or precipitation (was ~ed in furs and  
mounds — Richard Brautigan) SYN see SOAK — drench-er\ n

dress\ (dress\ v [ME, fr. MF dresser, fr. OF dreier, fr. (assumed) VL  
directus direct, pp. of dirigere to direct, fr. dis- + regere  
to straighten] — more at RIGHT] v (14c) 1 a : to make or set  
up b : to arrange (as troops) in a straight line and at proper  
distances 2 : to prepare for use or service; specif : to prepare for cook-  
ing on the table 3 : to add decorative details or accessories to  
clothing 4 a : to put clothes on b : to provide with clothing 5  
to dress down 6 a : to apply dressings or medications to b  
to arrange (the hair) by combing, brushing, or curling (2) : to  
groom and curry (an animal) c : to kill and prepare for market or for  
consumption — often used with out d : CULTIVATE TEND; esp : to  
manure or fertilize e : to put through a finishing process;  
to trim and smooth the surface of (as lumber or stone) ~ vi 1  
to put on clothing 2 : to put on or wear formal, elaborate, or  
fancy clothes (~ for dinner) 2 of a food animal : to weigh after being  
dressed — often used with out 3 : to align oneself with the next sol-  
dier in a line for celebration by hoisting national ensigns at the mastheads and  
running a line of signal flags and pennants from bow to stern

dress\ (1606) 1 : APPAREL CLOTHING 2 : an outer garment (as for a  
woman or girl) usu. consisting of a one-piece bodice and skirt 3 : cov-  
ering, adornment, or appearance appropriate or peculiar to a particular  
time 4 : a particular form of presentation : GUISSE

dress\ (1677) 1 : suitable for a formal occasion 2 : requiring or  
permitting formal dress (a ~ affair) 3 : relating to or used for a dress  
rehearsal — dress-sāz, dre-s\ n, often attrib [Fr. fr. dresser to train, drill, fr.  
ME (1366) : the execution by a trained horse of precision movements  
in response to barely perceptible signals from its rider

dress-circle\ n (1825) : the first or lowest curved tier of seats above the  
main floor in a theater or opera house

dress-code\ n (1968) : formally or socially imposed standards of dress  
dress-down\ n (ca. 1897) : to reprove severely ~ vi : to dress casually  
for reasons of fashion

dresser\ (dre-sər\ n (15c) 1 obs : a table or sideboard for preparing  
and serving food 2 : a cupboard to hold dishes and cooking utensils  
3 : a chest of drawers or bureau with a mirror  
dresser\ (1520) : one that dresses (a fashionable ~)

dresser\ n (ca. 1934) : a set of toilet articles including hairbrush,  
comb and mirror for use at a dresser or dressing table

dress-ing\ n (15c) 1 a : the act or process of one who dresses b : an  
instance of such act or process 2 a : a sauce for adding to a dish (as a  
salad) b : a seasoned mixture usu. used as a stuffing (as for poultry)

dress-ing\ material (as ointment or gauze) applied to cover a lesion b  
dressing material (as manure or compost)

dress-ing\ down\ (dre-sip-'daín\ n (ca. 1890) : a severe reprimand  
dressing-glass\ n (1714) : a small mirror set to swing in a standing  
frame and used at a dresser or dressing table

dressing-gown\ n (1777) : a robe worn esp. while dressing or resting  
dressing-room\ n (1675) : a room used chiefly for dressing; esp : a  
room in a theater for changing costumes and makeup

dressing-table\ n (1692) : a table often fitted with drawers and a mirror  
in front of which one sits while dressing and grooming oneself  
dress-maker\ 'dres-mā-kər\ n (1803) : one that makes dresses —  
dress-mak-ing\ -mā-kin\ n

dress-maker\ adj (1904) of women's clothes : having softness, rounded  
lines and intricate detailing (a ~ suit)

dress-rehearsal\ n (1828) 1 : a full rehearsal (as of a play) in costume  
and with stage properties shortly before the first performance 2 : a  
practice exercise for something to come : DRY RUN

dress-shield\ n (1884) : a pad worn inside a part of the clothing liable  
to be soiled by perspiration (as at the underarm)

dress-shirt\ n (1892) : a man's shirt esp. for wear with evening dress;  
a dress shirt

dress-uniform\ n (ca. 1897) : a uniform for formal wear  
dress-up\ v (1674) 1 a : to attire in best or formal clothes b : to  
make attractive or impressive like (a fiasco dressed up as a triumph) b  
to make more attractive, glamorous, or fancy (dress up a plain dessert  
with chocolate sauce) ~ vi : to get dressed up

dressy\ 'dres-ē\ adj dress-ier, -est (1768) 1 : showy in dress 2  
of a garment : smart — dress-i-ness\ n  
draw part of DRAW  
draw-sard\ 'drī-(y)ə-'sār(d), -drā-, -zār(d)\ n [F] (1898) : a de-  
fender or partisan of Alfred Dreyfus

drib\ 'drib\ n [prob. back-formation fr. dribble & dribbles] (ca. 1730) : a  
small amount — usu. used in the phrase dribs and drabs

drib-ble\ 'dri-bəl\ v drib-ble; drib-ble\ -(ə-)līn\ [freq. of drib (to  
dribble)] v (ca. 1589) 1 : to issue sporadically and in small bits 2  
: to let or cause to fall in drops little by little 3 a : to propel by suc-  
cessive slight taps or bounces with hand, foot, or stick b : to hit (as a  
baseball) so as to cause a slow bouncing ~ vi 1 : to fall or flow in  
drops or in a thin intermittent stream : TRICKLE 2 : to let saliva trickle  
from the corner of the mouth : DROOL 3 : to come or issue in piece-  
meal or desultory fashion 4 a : to dribble a ball or puck b : to  
proceed by dribbling c of a ball : to move with short bounces —  
drib-ble\ -(ə-)lār\ n

dribble\ n (ca. 1680) 1 : a tiny or insignificant bit or quantity 2 : a  
small trickling stream or flow 3 : an act, instance, or manner of drib-  
bling a ball or puck — drib-bly\ 'dri-b(ə-)lē\ adj

drib-let\ 'drib-lət\ n (1678) 1 : a trifling or small sum or part 2 : a  
drop of liquid

dried-up\ 'dri-dap, -dri-ə\ adj (1885) : being wizened and shriveled  
drier\ comparative of DRY

drier\ or dry-er\ 'dri-(ə-)r\ n (1528) 1 : something that extracts or  
absorbs moisture 2 : a substance that accelerates drying (as of oils,  
paints, and printing inks) 3 usu dryer : a device for drying  
driest\ superlative of DRY

drift\ 'drift\ n [ME; akin to OE drifan to drive — more at DRIVE] (14c)  
1 a : the act of driving something along b : the flow or the velocity  
of the current of a river or ocean stream 2 : something driven, prop-  
elled, or urged along or drawn together in a clump by or as if by a  
natural agency; as a : wind-driven snow, rain, cloud, dust, or smoke  
usu. at or near the ground surface b (1) : a mass of matter (as sand)  
deposited together by or as if by wind or water (2) : a helter-skelter  
accumulation c : DROVE, FLOCK d : something (as driftwood) washed  
ashore e : rock debris deposited by natural agents; specif : a deposit  
of clay, sand, gravel, and boulders transported by a glacier or by run-  
ning water from a glacier 3 a : a general underlying design or ten-  
dency b : the underlying meaning, import, or purport of what is spoken  
or written 4 : something (as a tool) driven down upon or forced  
into a body 5 : the motion or action of drifting esp. spatially and usu.  
under external influence; as a : the lateral motion of an aircraft due to  
air currents b : an easy moderate more or less steady flow or sweep  
along a spatial course c : a gradual shift in attitude, opinion, or posi-  
tion d : an aimless course; esp : a foregoing of any attempt at direc-  
tion or control e : a deviation from a true reproduction, representa-  
tion, or reading 6 a : a nearly horizontal mine passageway driven on  
or parallel to the course of a vein or rock stratum b : a small crosscut  
in a mine connecting two larger tunnels 7 a : an assumed trend to-  
ward a general change in the structure of a language over a period of  
time b : GENETIC DRIFT c : a gradual change in the zero reading of an  
instrument or in any quantitative characteristic that is supposed to  
remain constant SYN see TENDENCY — drift-y\ 'drift-ē\ adj

drift\ v (ca. 1600) 1 a : to become driven or carried along (as by a  
current of water, wind, or air) b : to move or float smoothly and ef-  
fortlessly 2 a : to move along a line of least resistance b : to move  
in a random or casual way c : to become carried along subject to no  
guidance or control (the talk ~ed from topic to topic) 3 a : to ac-  
cumulate in a mass or become piled up in heaps by wind or water b :  
to become covered with a drift 4 : to vary or deviate from a set course or  
adjustment ~ vi 1 a : to cause to be driven in a current b West  
: to drive (livestock) slowly esp. to allow grazing 2 a : to pile in  
heaps b : to cover with drifts — drift-ingly\ 'drift-īn-ē\ adv

drift-age\ 'drift-ij\ n (1768) : drifted material  
drift-er\ 'drift-ər\ n (1897) : one that drifts; esp : one that travels or  
moves about aimlessly

drift-fence\ n (1907) : a stretch of fence on rangeland esp. in the west-  
ern U.S. for preventing cattle from drifting from their home range

drift-net\ n (1848) : a fishing net often miles in extent arranged to drift  
with the tide or current and buoyed up by floats or attached to a boat

drift-wood\ 'drift-wūd\ n (1633) 1 : wood drifted or floated by water  
2 : FLOTSAM

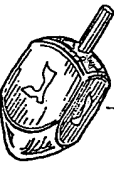
drill\ 'drill\ v [D drillen] v (1622) 1 a : to fix something in the  
mind or habit pattern of by repetitive instruction (~ pupils in spelling)  
b : to impart or communicate by repetition (impossible to ~ the sim-  
plest idea into some people) c : to train or exercise in military drill 2  
a (1) : to bore or drive a hole in (2) : to make by piercing action b  
: to shoot with or as if with a gun c (1) : to propel (as a ball) with  
force or accuracy (~ed a single to right field) (2) : to hit with force  
(~ed the batter with the first pitch) ~ vi 1 : to make a hole with a  
drill 2 : to engage in an exercise — drill-abil-ity\ 'dril-lə-'bi-lē\ n  
— drill-able\ -lə-bəl\ adj — drill-er\ 'dril-ər\ n

drill\ n (1611) 1 : an instrument with an edged or pointed end for  
making holes in hard substances by revolving or by a succession of  
blows; also : a machine for operating such an instrument 2 : the act  
or exercise of training soldiers in marching and in executing prescribed  
movements with a weapon 3 a : a physical or mental exercise aimed  
at perfecting facility and skill esp. by regular practice b : a formal  
exercise by a team of marchers c chiefly Brit : the approved or correct  
procedure for accomplishing something efficiently 4 a : a marine  
snail (Urosalpinx cinerea) destructive to oysters by boring through their  
shells and feeding on the soft parts b : any of several mollusks related  
to the drill 5 : a drilling sound

drill\ n [origin unknown] (1644) : a western African baboon (Papio  
leucophaeus syn. Mandrillus leucophaeus) having a black face and  
brown coat and closely related to the typical mandrill

drill\ n [perh. fr. drill (rill)] (1727) 1 a : a shallow furrow or trench  
into which seed is sown b : a row of seed sown in such a furrow 2  
: a planting implement that makes holes or furrows, drops in the seed  
and sometimes fertilizer, and covers them with earth

about\ 'əbət\ kitten, F table\ 'fə-təbəl\ further\ 'fə-ther\ ash\ 'æʃ\ ace\ 'eɪ\ mop, mar-  
\ 'mɑː\ out\ 'aʊt\ chin\ 'tʃɪn\ bet\ 'bet\ easy\ 'iːzi\ go\ 'ɡo\ hit\ 'hɪt\ ice\ 'aɪs\ job\ 'dʒɒb\  
sing\ 'sɪŋ\ law\ 'ləʊ\ boy\ 'bɔɪ\ thin\ 'θɪn\ the\ 'ði\ loot\ 'luːt\ foot\ 'fʊt\ yet\ 'jet\ vision\ 'vɪʒən\  
la, l, ce, ee, ue, i, see Guide to Pronunciation



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Webster's  
Third  
New International  
Dictionary  
OF THE ENGLISH LANGUAGE  
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surface finish to (a racetrack) esp. by scraping — *to* put on clothing (he *ed* quickly) (she *ed* slowly) *b* to put on or wear one's best clothes or formal clothes (he *ed* for the opera) — often used with *up* (he *ed* when given the chance) *c* to dress elaborately or *dress* (she *ed* up for a masquerade ball) *d* to wear by *ways* always — *in* good taste *e* *of a food* *animal* : to wear *with* one (the *ed* chicken *ed* four pounds) — *to* align oneself (the next soldier *ed* percent of his weight) *g* to dress one's hair *h* to dress one's face *i* to straighten — *dress* one's room *j* to give a *tr* a *tr* a dress ship *k* : to ornament a ship while it is at anchor *l* : to dress the heads and runnels of signal flags and pennants from bow to stern by *ways* *m* : to dress in honor of a special occasion (as a nation) *n* : to dress in courtesy to a foreign nation or a distinguished person *o* : to dress in the style of the U.S. Navy by *ways* *p* : to dress in the style of the national ensigns at the mastheads, the ship's largest flag, and the jack at the jackstaff *q* : to dress in the style of the act of making right or straight *r* : to dress in *redness* *s* : to dress in the human body as : *a* : clothing and accessories worn for a purpose or occasion (a soldier in : battle) *b* : a style of dress (the *ed* style) *c* : a style characteristic of a particular time or place (the *ed* of the 8th century) *d* : (Oriental) — (Arab) — *e* : a style of wearing clothes (conservative in ) (thout about his ) *f* : a garment (an evening dress for ladies) *g* : a piece of clothing made in one garment for females or a two-piece garment consisting of blouse and skirt or *h* : a covering, adornment, or appearance *i* : a particular time or place (the *ed* of the party) *j* : a style of dress (the *ed* of the party) *k* : a style of makeup and typographic *l* : a style of dress (the *ed* of the party) *m* : a style of dress (the *ed* of the party) *n* : a style of 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## THE EFFECT OF A MECHANICAL VENOUS PUMP ON THE CIRCULATION OF THE FEET IN THE PRESENCE OF ARTERIAL OBSTRUCTION

P. Gaskell, M.D., and J. C. W. Parrott, M.D., F.R.C.S.(C), *Winnipeg, Manitoba, Canada*

THERE is a need for an adequate conservative treatment for lesions and symptoms of the feet caused by severe arterial obstruction. Many patients with rest pain in the foot find relief by simply assuming a more erect posture. We have shown previously (9) that, when patients with arterial obstruction in the lower limbs assume a more erect posture, there is a slight increase in the local perfusion pressure beyond the obstruction and an increase in blood flow in the foot. However, this maneuver is not sufficient to relieve discomfort in some patients. To increase the perfusion pressure still further, we have added a mechanical venous pump in combination with the erect posture. This principle is not new. However, we have applied it in a slightly different way and have tried to obtain objective evidence of the effectiveness of our system.

### METHODS

All studies were carried out at a controlled room temperature of 20 degrees C. However, the patients were kept comfortably warm by an electric blanket, if necessary, on a circoelectric bed, which allowed easy change of posture from supine to sitting, to leaning-standing. The skin temperature of the dorsum of the foot was monitored throughout all protocols by a thermistor probe taped to the skin. The temperature of the foot was maintained between 33 and 35 degrees C. by comfortable body heat, insulating cotton pads about the foot within the boot and by judicious application of heat from an electric heating pad beneath the boot, when necessary. In most experiments, the foot temperature varied over a 0.5 to 1.0 degree C. range only.

The venous pump consisted of the arrangement illustrated in Figure 1. The foot, covered by a length of stockinette, was inserted into a boot made of a single layer of transparent flexible

vinyl plastic sheet. The toe of the boot was fitted with a large metal ring which was made airtight by the insertion of a rubber stopper. The stopper carried tubes for the inflation of the boot and for monitoring pressures. At the ankle, the boot was circled by a pneumatic cuff shaped to fit snugly on a cone. The cuff and the boot were connected to their own individual air pressure reservoirs. To operate the pump, the cuff was first inflated to the pressure desired in the boot. The pressure reservoir serving the boot was then opened with an available pressure above that in the cuff. The boot was quickly inflated to the pressure set by the pressure in the cuff, with the excess flow of air escaping from the boot under the cuff. Both cuff and boot were deflated again after 2 seconds. The pressure on the foot within the boot was thus regulated by the pressure in the cuff. An electronic timer controlled the time and period of inflation of the cuff or boot individually but in a linked and synchronized manner.

In the sitting position, the hydrostatic pressure in the veins and arteries of the foot is high. A brief inflation of the boot empties the veins of the foot, and the venous pressure remains reduced until the veins are refilled by forward flow of blood from the arteries. Removal of the hydrostatic pressure in the veins by the pump makes the unbalanced hydrostatic pressure on the arterial side available as a perfusion pressure to increase blood flow. The effectiveness of the pump in reducing venous pressure was studied by measuring the pressure directly in a vein on the dorsum of the foot in eight normal persons and in four patients with arterial obstruction. A cannula—20 gauge, 1½ inch—inserted into a vein with several tributaries was connected to a pressure transducer through a 4 foot long section of high pressure tubing and a three-way stopcock. Patency of the cannula was maintained by a continuous slow flow, approximately 0.1 milliliter per minute, normal saline solution through the side arm of the stopcock (6). The pressure transducer was supported at the level of the cannula in

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TABLE I—THE EFFECT OF POSTURE AND MECHANICAL VENOUS PUMP ON BLOOD FLOW OF THE FEET OF PATIENTS WITH ARTERIAL OBSTRUCTION

Patient No.	Age, yrs. Sex	Blood pressure	Supine systolic ankle pressure		Percentage increase in blood flow in test foot				
			Right	Left	On sitting I	Pumping test foot II	Pumping opposite foot III	(II-III)	Combined effect (I+II)
1	64 M	115/71	76	<15°	108	596	126	471	704
2	73 M	140/78	128	27°	12°	74	73	1	86
3	58 M	119/66	28°	73	202	9	8	1	211
4	63 M	114/70	70	30°	46†	212	-10	222	258
5	75 M	130/82	125	33°	242	43	-59	102	266
6	64 M	128/76	45°	85	63	-20	15	-35	43
7	65 M	113/68	48°	57	-2	14	-7	21	12
8	71 M	138/68	53	50°	135	0	11	-11	135
9	46 F	150/90	50°	93	13	7	22	-15	20
10	68 M	140/89	122	58°	83	120	-4	124	203
11	58 M	115/75	73	60°	112	263	65	198	374
12	63 M	110/66	60°	83	77	16	6	10	93
13	49 M	119/78	73	60°	31	60	-42	102	91
14	67 M	127/75	60°	70	22	63	-23	85	34
15	69 M	160/87	62°	103	39	151	-37	133	190
16	40 M	130/85	65°	115	17	6	1	5	22
17	66 M	124/80	65°	125	-43†	27	—	—	-17
18	54 M	140/68	76°	90	-34†	40	-23	63	6
19	77 M	160/77	143	80°	133	-7	-13	6	126
20	41 F	138/78	120	80°	-29	44	-14	58	15
21	53 M	127/75	123	32°	-30	16	9	7	-14
22	66 M	155/81	90	38°	-16	25	28	-3	9
No. of patients					22	22	21	21	22
Mean					53.7	79.9	6.3	75.9	133.5
S.E.M.					16.4	28.9	9.1	25.7	35.5
p value					p<0.01	p<0.02	p>0.01	p<0.01	p<0.002

†Test foot. The effect on blood flow of the posture and the venous pump was tested in the foot with the lowest ankle pressure.  
 ‡First change in posture only, not the average of two.

the vein of the foot, and pressure was recorded by a multichannel chart recorder.

The effectiveness of the compression pressures, ranging from 40 millimeters of mercury below to 40 millimeters of mercury above the venous pressure at the foot, compression periods of 0.5 to 4.0 seconds in increments of 0.5 second, compression frequencies of once every 5, 10, 15, 20 and 30 seconds and delay periods between inflation of cuff and boot of zero, 0.5, 1.0 and 2.0 seconds were tested for their effectiveness in reducing venous pressure with the person in the

seated position and in three subjects in the leaning-standing position.

The ability of the venous pump to increase the rate of blood flow in the foot was investigated by measuring its effect on the rate of clearance of  $^{133}\text{Xe}$  from a single injection just under the skin. Approximately 50 microcuries of  $^{133}\text{Xe}$  in 0.1 milliliter or less of normal saline solution was deposited just under the skin in the dorsum of the foot, 3 centimeters proximal to the toes, at least 20 minutes before any recording of the remaining radioactivity was begun.

The radioactivity remaining in the tissue was detected by a scintillation probe with sodium iodide crystal, suspended 6 centimeters above the  $^{133}\text{Xe}$  deposit and recorded in counts per minute at intervals of 30 seconds by a 400 channel analyzer. The counts per minute for each 30 second period were plotted on semilog graph paper. Best fit lines to relevant portions of the plot were drawn by inspection. Kety's clearance constant (14) was calculated from lines drawn to plots of clearance for at least 20 minutes for each circumstance of the protocol which will be outlined. Changes in rate of nutritional blood flow were considered to be proportional to changes in the clearance constants, and differences between the constants produced by the various maneuvers of the protocol were expressed as percentage change in blood flow. The clearance of  $^{133}\text{Xe}$  was ignored for the first 20 minutes or more after the injection and for the first ten minutes of every succeeding circumstance of the protocol.

The protocol for each blood flow study is illustrated in Figure 2. Clearance data were obtained from the same single injection of  $^{133}\text{Xe}$  during the following sequence of circumstances: A, patient supine—no pumping; B, sitting—no pumping; C, sitting—pumping test foot; D, sitting—no pumping; E, sitting—pumping opposite foot; F, sitting—no pumping, and G, supine—no pumping. The mean of  $\frac{B-A}{A} \times 100$  and  $\frac{F-G}{G} \times 100$  is given as the percentage increase in blood flow during sitting relative to supine posture. The percentage increase in blood flow resulting from pumping the test foot was given by  $\frac{C-0.5(B+D)}{0.5(B+D)} \times 100$ . Similarly, the percentage increase in blood flow resulting from pumping the opposite foot was given by  $\frac{E-0.5(D+F)}{0.5(D+F)} \times 100$ . The percentage increase in blood flow resulting from pumping the test foot, corrected for any reflex effect of the pumping, was given by subtracting from it the

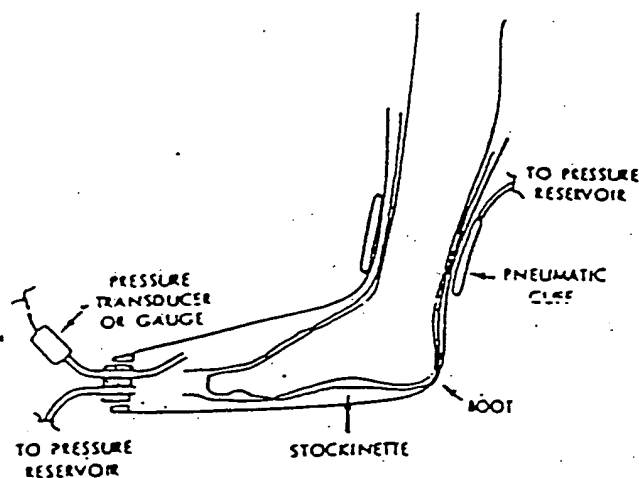


FIG. 1. Arrangement for the mechanical venous pump. The boot is made of transparent flexible vinyl sheet. The pneumatic cuff is first inflated to the pressure desired in the boot. The boot is then immediately inflated from its own pressure reservoir with a higher available pressure, the excess air escaping from the boot under the cuff when the cuff pressure is reached within the boot. The boot is inflated for 2 seconds every 15 seconds with the patient in the erect position.

percentage increase in blood flow caused by pumping the opposite foot. The total effect of venous pumping in the test foot and of the sitting posture, relative to the blood flow while supine, was taken as the sum of the individual effects. In five of 22 patients, the order of C and E in the protocol was reversed, and calculations were adjusted accordingly. On the basis of the venous pressure studies, the venous pump was set to compress the foot for 2 seconds every 15 seconds with a compression pressure approximately 10 millimeters of mercury greater than the estimated venous pressure at the foot and a delay of 0.5 second between the inflation of the cuff and the boot. Brachial blood pressure was measured by auscultation during each part of the protocol. Some essential information about the 22 patients in whom satisfactory clearance data were obtained is given in Table I. The severity of the obstruction in the arteries supplying the lower

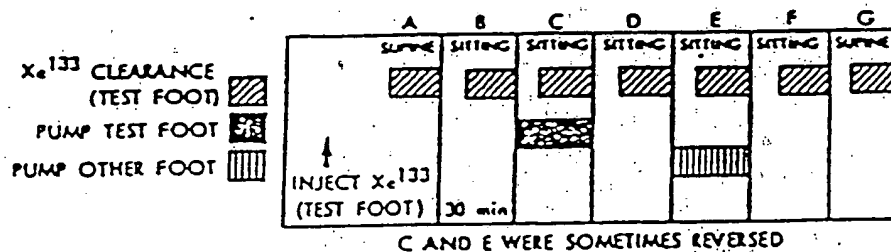


FIG. 2. The protocol for the effect of mechanical venous pump combined with erect posture on blood flow is illustrated. The letters A, B, C, D, E, F and G are used in the text to refer to the circumstances indicated here.



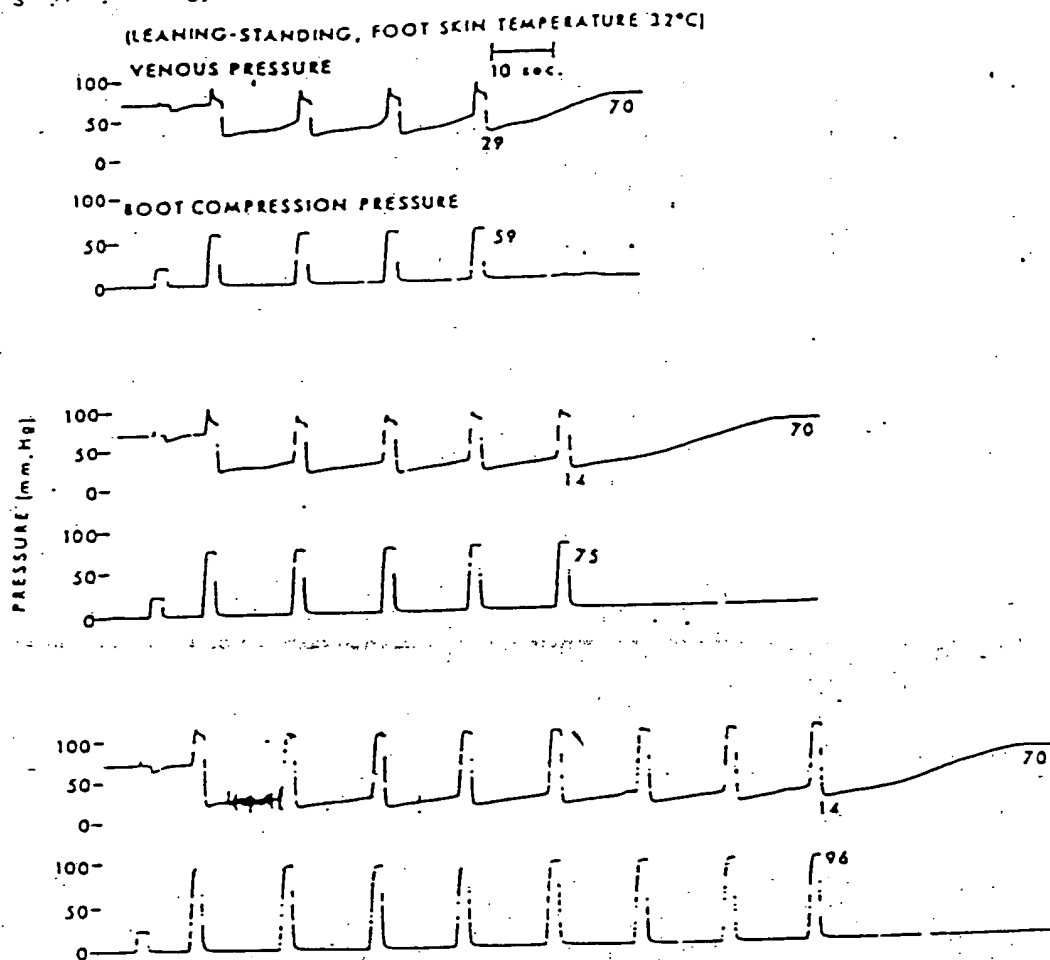


FIG. 3. The three tracings illustrate the effectiveness of different compression pressures in emptying the veins of the foot during venous pumping in a patient with arterial obstruction. The figures below the venous pressure curves are the minimum pressures attained by pumping and the maximum pressure in the absence of pumping in the leaning-standing patient who had a supine ankle blood pressure of only 35 millimeters of mercury. There was an average gain of about 50 millimeters of mercury in perfusion pressure at the foot during venous pumping.

limbs is indicated by the local systolic blood pressure measured at the ankles by a spectroscopic method (7, 8) when the patient was supine. In each patient, the test foot chosen for study was that which had the lowest pressure at the ankle. In all but three patients, there was evidence of bilateral arterial obstruction. Atherosclerosis obliterans was the cause of obstruction in all. Patients 1, 2, 20 and 21 also had diabetes mellitus. Patient 18 had had frostbite of the right—test—foot. Intermittent claudication was the common symptom, but Patients 1, 2, 3, 5, 8 and 11 had rest pain.

#### RESULTS

**Venous pressure studies.** In Figure 3 are shown some of the results obtained in Patient 21 while leaning-standing, and the venous pressure in the foot was 70 millimeters of mercury. Sys-

tolic blood pressure at the level of the ankle measured while supine was 35 millimeters of mercury, while the brachial pressure was 133/70 millimeters of mercury. During venous pumping, the foot was compressed every 15 seconds for 2 seconds, with the compression pressures being shown. The delay between inflation of the cuff and foot was 0.5 second. It is apparent that, although a compression pressure below the initial venous pressure did reduce venous pressure, a better and more long lasting reduction was obtained with a compression pressure slightly higher than the initial venous pressure. However, there was no advantage in using a compression pressure of 96 millimeters of mercury rather than 75 millimeters of mercury. Venous pressure was maintained at a low average level of approximately 20 millimeters of mercury between compressions. The rise in venous pressure fol-

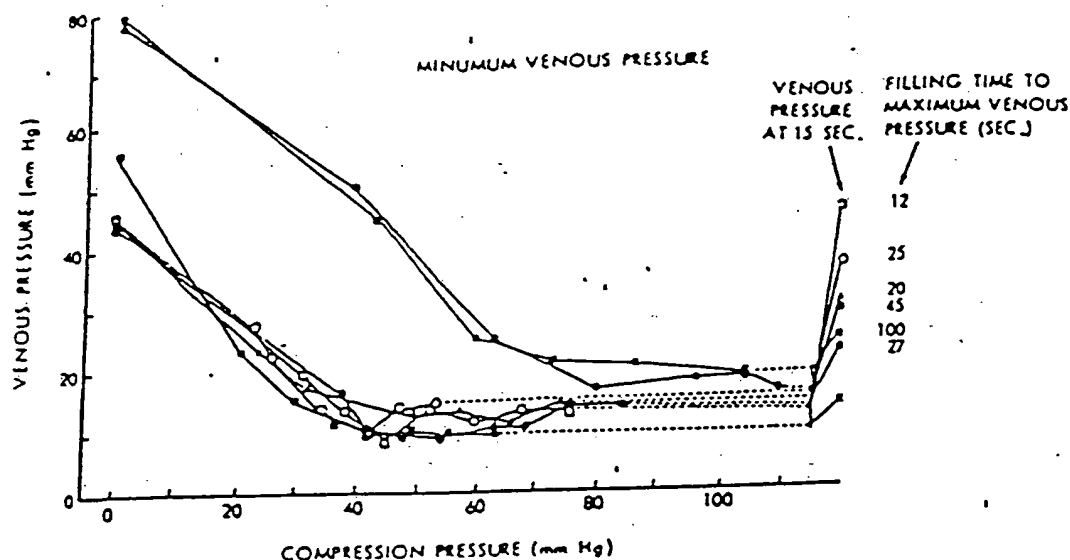


FIG. 4. The reduction of venous pressure during venous pumping with various compression pressures in five normal persons when compression for 2 seconds occurred every 15 seconds. Each point in the minimum venous pressure section indicates the lowest venous pressure produced. Venous pressure at 15 seconds was the pressure reached 15 seconds after the last compression and immediately before the next.

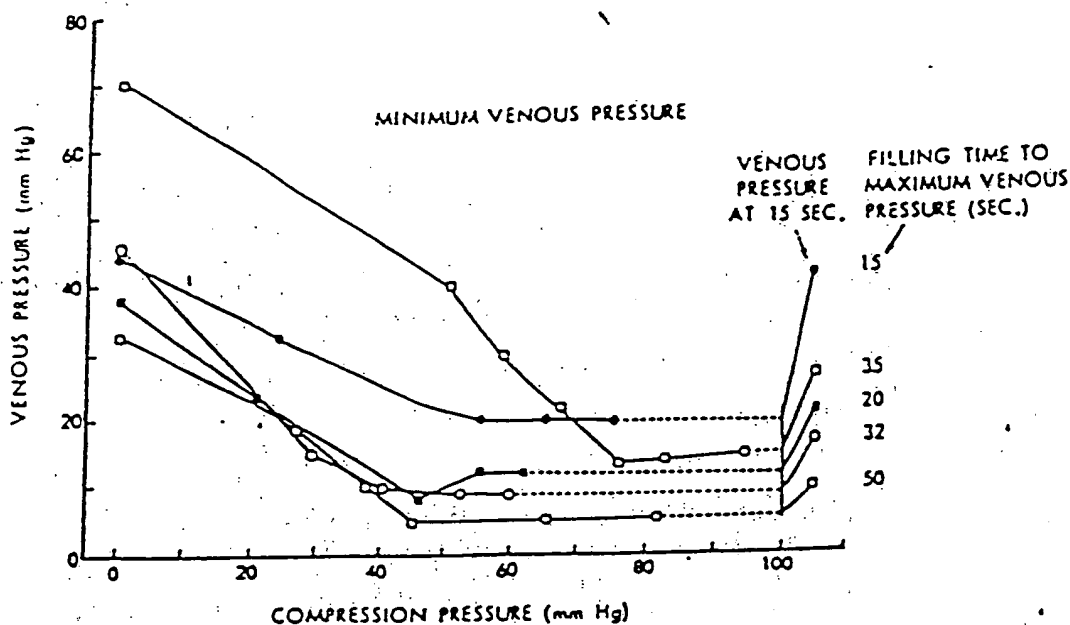


FIG. 5. The same as Figure 4, except that the results were obtained for the four patients with arterial obstruction. Their supine ankle blood pressure, millimeters of mercury, at the time is given in parentheses. □, Patient 21 (35); ■, Patient 23 (65); ○, Patient 4 (30); ●, Patient 24 (38).

lowing the last compression was slow during the first 15 seconds but then became more rapid. In this example, the perfusion pressure between compressions was increased by about 50 millimeters of mercury. The effectiveness of the pumping was not improved under these circumstances by increasing the compression period from 2.0 to 2.5 or 3.5 seconds. However, a

compression period of 1 second did not reduce venous pressure as well, and venous filling was more rapid. When this patient was sitting and venous pressure in the foot rose to a maximum of 35 millimeters of mercury, the venous pump reduced it to 5 millimeters of mercury.

We found, in general, that a compression pressure several millimeters of mercury higher than

the maximum venous pressure at the foot was necessary for most efficient pressure reduction. A compression period of 2 seconds was the minimum at which one could be sure of an adequate pressure reduction; 1 second was often too short and periods longer than 2 seconds were unnecessary and reduced efficiency. The shortest delay possible between inflation of cuff and boot is satisfactory, even no delay; however, we have usually used 0.5 second. In Figures 4 and 5, the venous pressure reductions which we obtained in all the persons and patients with the parameters already suggested are illustrated. They also indicate why we have chosen not to use a compression interval of longer than 15 seconds, even in patients with arterial obstruction.

**Blood flow studies.** The percentage changes in blood flow ascribed to the various maneuvers for each individual patient are given in Table I. For all patients, the mean change resulting from each maneuver and its statistical significance based on a *t* test are also shown.

The magnitude of change in blood flow when the posture was altered from supine to sitting varied widely, as might be expected when opposing influences are in play. Reflex vasoconstriction of variable degree will tend to reduce blood flow, and in the normal person, flow usually is reduced (9). In four normal young women, ages 25 to 34 years, studied along with the patients in this investigation, the blood flow fell by 60, 58, 18 and 14 per cent, respectively, on changing to the sitting posture. In the patients, however, the effect of reflex vasoconstriction is opposed by distention of collateral vessels which may be poorly or well developed in individual patients and by distention of small resistance vessels previously under some degree of reduced transmural pressure. The distention of collaterals leads to a greater increase in local arterial pressure at the foot than would be expected from just the height of the hydrostatic column of blood. Thus, in a few patients at the time of measurement, the rate of blood flow was decreased slightly by the change in posture, but in most, it was increased. The mean increase of about 54 per cent was significant,  $p < 0.01$ . The patients are arranged in Table I in ascending order of their supine ankle systolic blood pressure. If one looks more closely at the distribution of increases in blood flow and their magnitude among the patients in relation to their supine ankle blood pressure, it is evident that the greater increases occur in those patients with the lower ankle pressure and that there appears to be a level of ankle pressure, about 60

millimeters of mercury, above which the blood flow is more likely to decrease on assuming the erect posture, as it does in normal persons. Therefore, the effect in patients with an ankle pressure of 60 millimeters of mercury or less was compared with that in patients with greater ankle pressure. The mean increase in the former group, number equals 14, was  $81.7 \pm 19.4$  per cent S.E.M.,  $p < 0.002$ , whereas, in the latter group, it was only  $4.6 \pm 20.84$  per cent S.E.M.,  $p > 0.1$ . The percentage increase in blood flow was significantly greater in the patients with the lower ankle pressures,  $p < 0.05$ .

Venous pumping in the test foot also caused widely varied increases in blood flow and, in two of the patients, a slight fall in flow. But again, variations in neurogenic vasoconstriction will play a part in the over-all response. With continued and repeated use of the venous pump, one might expect that any reflex vasoconstriction it generates would decrease. The amount of increase in rate of blood flow will depend also on the ratio of reduction of venous pressure to the existing local arterial pressure at the foot. For example, the extremely large percentage increase in flow rate for Patient 1 is what one might expect if the initial perfusion pressure were only about 10 millimeters of mercury. It should be noted that Patients 1 and 11 had previously undergone sympathectomy involving the test foot. This would obviate any reflex vasoconstriction. The mean increase in blood flow for all patients of about 80 per cent was significant,  $p < 0.02$ , but again, the mean increase for the 14 patients having ankle pressures of 60 millimeters of mercury or less was  $104.1 \pm 43.73$  per cent S.E.M.,  $p < 0.05$ , and for the remaining eight patients,  $33.7 \pm 17.23$  per cent S.E.M.,  $p > 0.05$ . However, statistically, the mean of the increases in the former group of patients was not greater than the mean for the patients with ankle pressures greater than 60 millimeters of mercury,  $p > 0.1$ , because of the wide variation among the increases.

Venous pumping in the opposite foot resulted in an over-all increase in blood flow of about 6 per cent, which was not significant,  $p > 0.1$ . Therefore, while reflex effects may have varied from one patient to another during the procedure, the effect was negligible for the group. When the increase in flow resulting from pumping of the test foot was corrected in the individual patient by subtracting the increase caused by pumping the opposite foot, the mean increase for all patients was still about 76 per cent,  $p < 0.01$ .

This rate is, in effect, the direct local result of the pump on local blood flow. The mean, corrected increase for the 14 patients with ankle pressure of 60 millimeters of mercury or less was  $91.1 \pm 36.28$  per cent S.E.M.,  $p < 0.05$ , and for the remaining seven patients, it was  $46.3 \pm 25.73$  per cent S.E.M.,  $p > 0.1$ . These mean increases were not significantly different,  $p > 0.1$ . Throughout the protocol, the systemic arterial blood pressure remained fairly stable, usually not varying by more than 12 millimeters of mercury. The greatest changes generally occurred with a change of posture from supine to sitting. However, in almost all instances, the larger changes in systemic pressure were in the opposite direction to the change in blood flow. A consideration of changes in blood pressure relative to changes in the rate of blood flow indicated that they could not account for the alterations in rate of flow.

It is apparent that the erect posture and venous pumping each favor an increase in blood flow in the foot in the presence of fairly marked arterial obstruction. The combined effect was a mean increase for all patients of  $133.5 \pm 35.5$  per cent S.E.M.,  $p < 0.002$ . For the patients with an ankle pressure of 60 millimeters of mercury or less, the mean combined increase in flow was  $185.7 \pm 49.63$  per cent S.E.M.,  $p < 0.01$ , and for patients with greater ankle pressure,  $42.1 \pm 14.89$  per cent S.E.M.,  $p < 0.02$ . The mean combined increase was significantly greater,  $p < 0.02$ , in the patients with ankle pressures of 60 millimeters of mercury or less (Fig. 6). Of the six patients who had rest pain, Patients 1, 2 and 3 were not relieved by postural change alone but were during venous pumping. In addition, four patients, not included in Table I, were unable to complete all phases of the protocol because of severe rest pain when just lying or sitting quietly. However, all four patients had relief of rest pain during venous pumping of the foot.

#### DISCUSSION

Treatment of extremities exhibiting signs and symptoms of ischemia by posture or by some form of mechanical aid to increase blood flow in the part is quite an old concept. Herrmann and Reid (12) reviewed several early articles, in which the principle of reducing the atmospheric pressure acting on a part to create suction and enhance blood flow in the region was used in the treatment of various ailments, including ischemia of the extremities. Reid and Herrmann (11, 12, 13, 19) have reported on the use of their own apparatus for the subjection of an ischemic limb to

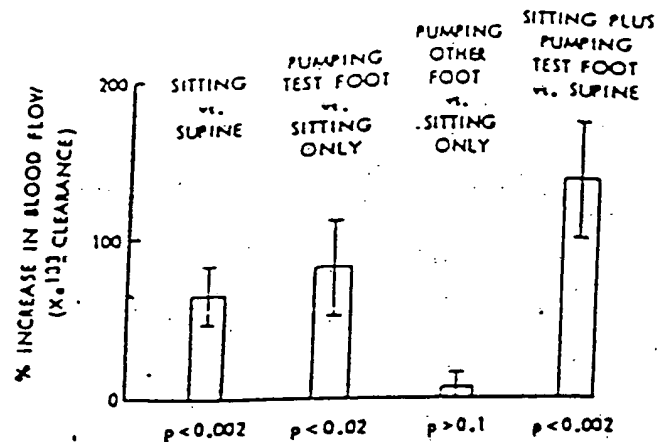


FIG. 6. Summary of the mean percentage increases in blood flow in the forefoot produced by change in posture or venous pumping, or both, in 22 patients with arterial obstruction of various degree.

alternating negative and positive pressure passive vascular exercise—to increase local blood flow. They demonstrated an increase in local skin temperature during the use of the apparatus and claimed some clinical success with it.

Several authors reported favorable clinical results from the use of the Herrmann apparatus. However, Allen and Brown (1) urged caution in the assessment of the results, stating that, "Our own opinion is that good results ordinarily follow changing environmental pressure treatment in cases in which good results could be expected from other measures, and that when good results do not follow other measures, passive vascular exercise is usually valueless." Nevertheless, they commented that, "The greatest benefit we have observed from this treatment is in the relief of the pain of ischemic neuritis."

About the same time, Landis and Gibbon (16) also designed an apparatus for applying alternating negative and positive pressure to an ischemic limb to increase blood flow to the extremity. They (16) also were able to demonstrate quite clearly that their procedure could produce and maintain an increase of the local skin temperature. Clinical improvements of certain categories of ischemic signs and symptoms in the lower extremity were claimed because of its use (15, 17).

There were perhaps two significant differences between the procedure of Herrmann and Reid (12, 13) and that of Landis and Gibbon (16). In the former procedure, the patient was supine in bed, with the leg under treatment being slightly elevated above heart level, and the external pressure on the part was changed slowly—alternating between plus 20 and minus 80 millimeters of mercury—over a cycle period of 15

seconds or longer. The Landis and Gibbon (16) apparatus changed pressures rapidly, in cycles of negative pressure of minus 120 millimeters of mercury for 25 seconds, positive pressure of plus 80 to 100 millimeters of mercury for 5 seconds, while the patient was semirecumbent or sitting up in bed. The feet were, therefore, well below heart level. The conditions were favorable for enhancing flow with only quite brief interruption.

In spite of the early clinical impressions of the usefulness of these negative pressure pumps, their use was apparently soon abandoned. Sanders (20) introduced the rocking or oscillating bed initially for the treatment of edema of the feet and legs by regular postural changes to empty completely and fill the veins and capillaries intermittently. He subsequently used the bed to treat patients with peripheral vascular disease with some success in relieving pain and in healing ulcers. Barker and Roth (3) also reported "... relief of pretrophic pain, pain of ischemic neuritis, and the pain which was associated with ulceration and gangrene by use of the bed." They found "... that adjustments of the bed were usually necessary for each patient, that it was usually advisable to run the Sanders bed at a rather rapid speed (cycle of two minutes), and that it was desirable to have the feet of the patient just become blanched when they were in the elevated position and just develop rubor when they were in the dependent position before the direction of motion changed." In spite of these clinical reports, the Sanders oscillating bed also seems to have been abandoned.

It is a well known fact that many patients who experience ischemic rest pain in the foot when supine may obtain relief by changing to a more erect posture and perhaps taking a few steps around the room. One presumes there must be an increase in blood flow through the ischemic area to relieve the pain. Dahn and colleagues (5) measured an increase in rate of clearance of  $^{133}\text{Xe}$  from anterior tibial muscle when patients with obstruction of arteries supplying the lower limb changed from the supine to the sitting position. In one patient, they measured an increase in blood flow in the foot by plethysmography under the same circumstances. Gaskell and Becker (9) found that the  $^{133}\text{Xe}$  clearance rate from dermal tissues of the forefoot was increased in patients with arterial obstruction upon assuming the more erect posture but that, in normal persons, reverse was usually observed. Dahn and associates (5) thought that the increased flow in the erect posture resulted from greater distention of

resistance vessels, previously under low transmural pressure in the ischemic area, by the rise in hydrostatic blood pressure. Gaskell and Becker (9) identified an additional factor responsible for the increased flow in the patients. The increased hydrostatic pressure in collateral vessels when the patient was erect distended them also, reducing their resistance to flow so that less pressure energy was lost by the blood passing through. Thus, the increase in local arterial blood pressure at ankle level on changing to the erect posture was found to be greater than expected on a simple hydrostatic basis and greater than observed in normal persons. The arteriovenous pressure difference might be increased by 10 to 12 millimeters of mercury, which could mean an increase in perfusion pressure of 20 or 30 per cent in a severely ischemic extremity.

Buerger (4) attempted to increase blood flow to the feet by the use of postural exercises. He expected that the increased ischemia produced when the foot was elevated would lead to greater flow through the foot when it was made dependent because of reactive hyperemia. However, Scheinberg and co-authors (21) recognized that the real value of such postural exercises was in the gain in perfusion pressure at the foot, the veins of the leg having been drained when the leg was elevated and, because of their valves, having very low hydrostatic pressure in them when made dependent until they were again filled by enhanced blood flow through the capillary bed resulting from an unbalanced increase in hydrostatic pressure in the arteries. Scheinberg and co-workers (21) suggested that a mechanical venous pump to empty intermittently the veins of the foot by brief compression in the erect position would increase blood flow in an ischemic foot in the same way. They showed that, with the foot in a water-filled plethysmograph and the person standing, a brief compression of the foot by a pressure slightly higher than venous pressure, exerted through air pressure on the water, would increase the rate of blood flow by 200 to 300 per cent over the flow rate measured in the same way after a brief compression but with the person in the supine position. However, their study did not separate the effect of the erect posture from that of the venous pump on the rate of flow.

Allwood (2) and Loane (18) used a pneumatic cuff, 8, 10 or up to 20 centimeters wide, at the lower part of the calf, briefly inflated at quite short intervals to milk the blood out of the veins of the foot. On the basis of plethysmographic measurements reported by Allwood (2) or plethys-

mographic, heat flow or heat elimination studies by Loane (18), both concluded that the rate of blood flow was increased by this procedure in the seated normal person (2, 18) or in patients with arterial obstruction (2). The effect of posture itself on rate of flow was not studied.

Perhaps the most pertinent recent work is that by Henry and Winsor (10). To explain the relevance of our work to theirs, it is necessary to give certain details of their procedures. They measured the effect on the clearance rate of  $^{131}\text{I}$  from the skin fold of the toes and also from the adductor muscle of the fifth toes of massaging the calf of the leg. A bag which covered the leg from the head of the fibula to the maleoli was inflated for a short time at intervals to reduce venous pressure at the foot in the seated person. The clearance rate was measured during a 30 minute period, alternately, from the foot of the test and the control leg. Massaging reduced venous pressure at the foot to about 45 millimeters of mercury although Henry and Winsor (10) indicated that more distal massage would be more effective in lowering venous pressure.

In normal persons, the clearance of  $^{131}\text{I}$  was found to be more rapid in the foot of the leg which was massaged than in the control foot. Compression pressure for massage was 60 to 100 millimeters of mercury applied for 3 to 5 seconds, with an off period of 15 to 20 seconds. However, in patients with arterial obstruction, the compression with 60 to 100 millimeters of mercury was applied for 15 seconds, with an off period of 35 to 40 seconds. Again, the clearance rate was greater from the foot of the massaged leg than from the control foot during massage. In addition, in further experiments, it was observed that the clearance rate remained greater from the test foot than from the control foot half an hour after the end of the massage period, suggesting that massaging had produced an increase in blood flow through the foot that lasted well beyond the period of actual massage. These results pertain to the effect of the massaging on the rate of flow and not to any effect of the erect posture alone. We did not observe a long continued increase in clearance rate of  $^{133}\text{Xe}$  beyond the end of the venous pumping. It should be noted that Henry and Winsor (10) did not have prior clearance rates from the same foot with which to compare clearance rates obtained either during or after the leg massage nor was any comparison made of clearance rates between the control and test feet before massaging the test leg. Therefore, it is possible that the relative clearance rates measured

after the end of massage represent, in fact, the rates that might have obtained before any massaging took place. The fact that, in the experiments of Henry and Winsor (10), the observed differences between clearance rates in test and control feet after the massaging are similar to, and not less than, the differences measured during massaging, when one would expect the massaging to increase the clearance rate in the test feet may be explained thusly. We would expect that the compression for 15 seconds in the patients with pressures of 60 to 100 millimeters of mercury at the level of the calf where the sum of supine local arterial blood pressure, for example, 40 to 50 millimeters of mercury, and the hydrostatic pressure to calf, not foot, level when seated, for instance 40 to 50 millimeters of mercury, would seriously hinder, if not prevent, arterial flow during that period in the patients with more severe obstruction. Whatever flow did continue would be raising venous pressure over 15 seconds, reducing the perfusion pressure over that period. Thus, we consider that the higher rate of clearance of  $^{131}\text{I}$  from the ischemic foot during massage of the leg may not have been the result of massaging or represent any further increase in blood flow. Other factors, such as the difference in the effect of posture on clearance rates from two feet when the arteries in the two legs are not obstructed to the same degree, may influence the relative clearance rates. We are not told of the bilateral involvement by obstruction or which of two legs not symmetrically involved was chosen as the test leg. It should also be noted that separate similar injections of the radioactive material, even into the same foot, do not necessarily show the same clearance rates.

In the present work, we have confirmed our previous results which showed that the more erect posture will increase the rate of blood flow through the foot of an ischemic limb, but not usually in the foot of a normal limb. The mechanical venous pumping provides an additional increase in flow. The sum of these increases was, on the average, 133.5 per cent. But in those patients in whom the supine ankle pressure was 60 millimeters of mercury or less, the combined effect was an increase of 185.7 per cent, significantly greater than the 42.1 per cent increase produced in patients with higher supine ankle pressures,  $p < 0.05$ . Although the absolute increases in blood flow were not measured—or calculated—and may not be great, they are, nevertheless, important to a precarious extremity, as indicated by the relief of rest pain. The

venous pumping in addition to increasing perfusion pressure will also tend to prevent edema formation when the feet are so dependent.

The form of boot used to provide the pumping deserves comment. We consider that a double walled boot, inflated so that the inner wall is pressed to the skin, may distort and traumatize tissue which already has poor nutrition and healing properties. Pressure of air directly on the foot should be less disturbing. It is hoped that confining a cuff pressure on the skin to the area above the ankle will avoid adverse consequences with prolonged use. Henry and Winsor (10) suggested that a boot which covered both the calf and foot may provide better emptying of the veins and a lower venous pressure at the foot. We have found that the boot covering the foot alone is simpler, less cumbersome and gives a greater reduction of venous pressure than either a large cuff which covers the whole calf or a boot which includes the calf and the foot. By using only positive pressure combined with posture rather than positive and negative pressure, a cumbersome rigid boot and sealing difficulties are avoided. Since only the foot is included in a single layered boot, it is hoped that a form of boot and pump may be developed which will allow a patient under treatment a reasonable degree of mobility.

#### SUMMARY

A boot of single layer, flexible vinyl sheeting and a pneumatic cuff encircling its top at the ankle, each independently inflatable, constitute a mechanical venous pump. Inflation of the cuff to the desired boot pressure is followed immediately by inflation of the boot from a reservoir with higher available pressure than that in the cuff. When the boot pressure reaches cuff pressure, the excess air escapes from the boot under the cuff. A low venous pressure at the foot could be maintained by compressing the foot for 2 seconds every 15 seconds with a pressure which is 10 millimeters of mercury above initial venous pressure. In seated patients with arterial obstruction whose supine ankle blood pressure was 60 millimeters of mercury or less, the rate of blood flow in the skin of the forefoot was increased by  $104.1 \pm 43.7$  per cent S.E.M.,  $p < 0.05$ , during venous pumping. In these patients, a change in posture alone from supine to sitting increased the rate of blood flow by  $81.7 \pm 19.47$  per cent,  $p < 0.002$ . The combined effect of the erect pos-

ture and venous pumping was an increase of  $185.7 \pm 49.63$  per cent,  $p < 0.01$ . Rest pain was relieved by the combined effect.

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☐ **BLURRED OR ILLEGIBLE TEXT OR DRAWING**

☐ **SKEWED/SLANTED IMAGES**

☒ **COLOR OR BLACK AND WHITE PHOTOGRAPHS**

☐ **GRAY SCALE DOCUMENTS**

☒ **LINES OR MARKS ON ORIGINAL DOCUMENT**

☐ **REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**

☐ **OTHER:** \_\_\_\_\_

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